IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JOHN KELLEY, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 4:20-cv-00283-O

DEFENDANTS' BRIEF IN SUPPORT OF RESPONSE TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION FOR SUMMARY JUDGMENT

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SUMMARY

Under the Affordable Care Act, most health insurance plans must cover certain preventive services free of charge (42 U.S.C. § 300gg-13) (the "Preventive Services Provision"). The Preventive Services Provision ensures that insureds have access to potentially life-saving medical services, such as basic cancer screenings for breast, ovarian, cervical, lung and colorectal cancers; vaccinations for diseases such as polio; care for pregnant women and infants including screenings for gestational diabetes and preventive eye medication for newborns; and vision screening for small children.

Plaintiffs ask this Court to invalidate the Preventive Services Provision. They have not been required to avail themselves of services they do not want, and they cannot demonstrate that the availability of the services has *any* effect on their own premiums; indeed, some of the Plaintiffs have chosen, for independent reasons, to obtain no health insurance at all. Nonetheless, in an effort that would have the effect of depriving absent parties of potentially life-saving healthcare services, Plaintiffs contend that the Preventive Services Provision violates the Appointments Clause and the nondelegation doctrine, and that a portion also violates the Vesting Clause.

Because Plaintiffs fail to establish standing for their claims, this Court has no jurisdiction to hear this case. Even if Plaintiffs had standing, the Preventive Services Provision does not violate the Constitution. The Secretary of Health and Human Services (the "Secretary"), a duly appointed principal officer of the United States, has independently ratified all recommendations and guidelines currently subject to the coverage requirements of the Preventive Services Provision, curing any putative defect in the appointments of the entities and officials who issued the guidelines and recommendations in the first instance. *See, e.g.*, *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019).

In any event, the Secretary's ratification was unnecessary, as there was no Appointments Clause problem to begin with: Three of the four sets of guidelines and recommendations take effect only on the acceptance of an inferior officer of the United States—the Director of the Centers for Disease Control and Prevention ("CDC") and the Administrator of the Health Resources and

Services Administration ("HRSA")—each of whom is superintended, appointed, and can be dismissed by the Secretary. And the fourth set of recommendations is issued by an independent body that does not exercise Executive Power and is not subject to the Appointments Clause; that body's standards have been appropriately incorporated into law by Congress.

Nor does the statute violate the nondelegation doctrine, as Congress's delegations in the statute fall well within the bounds that the Supreme Court has found to be constitutional and that the Fifth Circuit has "uniformly upheld." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 442 n.17 (5th Cir. 2020).

In addition to their constitutional claims, certain Plaintiffs also assert that requiring coverage of one particular preventive service under the statute—antiviral medications to prevent HIV (preexposure prophylaxis, or "PrEP" medications)—violates the Religious Freedom Restoration Act ("RFRA"). But Plaintiffs cannot create a genuine issue of material fact as to whether RFRA even applies, and in any event, the requirement that most insurance plans cover PrEP medications is the least restrictive means of furthering the unquestionably compelling government interest of preventing the spread of a deadly disease.

BACKGROUND

A. Statutory and Regulatory Background

The Preventive Services Provision of the Affordable Care Act ("ACA") provides that most health coverage "shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for" four categories of preventive care services. 42 U.S.C. § 300gg-13(a). Three entities affiliated with the Department of Health and Human Services (HHS) play a role in identifying the services that fall within those categories. First, plans must cover "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force." *Id.* § 300gg-13(a)(1). Second, plans must cover "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the

individual involved." *Id.* § 300gg-13(a)(2). Third, "with respect to infants, children, and adolescents," plans must cover "evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration." *Id.* § 300gg-13(a)(3). And fourth, "with respect to women," they must cover "such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration[.]" *Id.* § 300gg-13(a)(4).

The three entities named in the Preventive Services Provision have different structures and organizations and are governed by different statutes, regulations, and other organizing documents. Two of the three entities—HRSA and CDC—are within the Public Health Service, a component of HHS, acting under the direction of and carrying out the authority of the presidentially-appointed and Senate confirmed Secretary. *See*, Reorganization Plan No. 1 of 1953 § 1, 5 U.S.C. app. 1 (stating that Secretary of Health, Education, and Welfare "shall be appointed by the President by and with the advice and consent of the Senate"); 42 U.S.C. § 3501; 20 U.S.C. § 3508(b) (redesignating Secretary of Health, Education, and Welfare as the Secretary of Health and Human Services). The third entity, the United States Preventive Services Task Force ("PSTF"), is an independent volunteer body assisted by, but not part of, the federal government.

1. The United States Preventive Services Task Force

The PSTF is not a federal agency, but a volunteer body of "nationally-recognized non-Federal experts in prevention and evidence-based medicine." APP 066, USPSTF Procedure Manual § 1.3. Its "mission is to improve the health of [all Americans] by making evidence-based recommendations about clinical preventive services and health promotion." APP 066, *id.* § 1.1; *see* APP 067, *id.* § 1.4 (PSTF "comprehensively assesses evidence and makes recommendations about the effectiveness of clinical [and] primary and secondary preventive services"); *see also* 42 U.S.C. § 299b-4(a)(1) (PSTF "shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of

developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services[.]").

The PSTF's recommendations are typically published in peer reviewed journals, not government publications like the Federal Register. *See* APP 077, *id.* §1.10. By law, "[a]ll members of the Task Force . . . and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure." 42 U.S.C. § 299b-4(a)(6). The PSTF is thus not a government agency and does not articulate the position of the United States government. As its published recommendation statements make clear, "[r]ecommendations made by the USPSTF are independent of the US government. They should not be construed as an official position of AHRQ or the US Department of Health and Human Services." APP 162, PrEP Recommendation Statement at 2211.

The PSTF is supported by the Agency for Healthcare Research and Quality ("AHRQ"), a federal agency within HHS, whose role is to "provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the [PSTF]'s recommendations." 42 U.S.C. § 299b-4(a)(3).

The PSTF is "convened" by the AHRQ Director and is currently comprised of 16 members. *See id.* § 299b-4(a)(6); APP 067, USPSTF Procedure Manual § 1.5. The AHRQ Director selects PSTF members for a four-year term, *id.* §§ 1.5.1 & 1.5.2, but PSTF members do not have any specific tenure protections and are thus removable at will.

2. The Advisory Committee on Immunization Practices ("ACIP")

ACIP is a federal advisory committee subject to the Federal Advisory Committee Act, 5 U.S.C. app. 2. It exists to "provide advice and guidance to the Director of the CDC regarding use of vaccines." APP 148, ACIP Charter at 1. It was established pursuant to 42 U.S.C. § 217a, which authorizes "[t]he Secretary [to] . . . appoint such advisory councils or committees . . . for such periods of time, as he deems desirable . . . for the purpose of advising him in connection with any

of his functions." 42 U.S.C. § 217a. Members are selected by the Secretary, *see* APP 151, ACIP Charter at 3, and serve four-year terms, *id.* at 4, but are removable at will.

As its name suggests, ACIP's recommendations are purely advisory. ACIP "reports to the Director," of CDC. APP 149, *id.* at 2. For its advisory recommendations to take effect, the CDC Director, "by delegation" from the Secretary of HHS, must "adopt[]" ACIP's recommendations. APP 148, *id.* at 1; *see also* 45 C.F.R. 147.130(a)(1)(ii) ("[A] recommendation from [ACIP] is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention"). Once "adopted" by the CDC Director, ACIP's recommendations are published in CDC's Morbidity and Mortality Weekly Report. *See* APP 148, ACIP Charter at 1. The CDC Director can decline to adopt ACIP's recommendations, and has done so in the past, albeit infrequently. *See infra note* 26.

The CDC Director, in turn, is the head of CDC, an agency of the Public Health Service and component of HHS. *See infra* note 21. As an "officer[] . . . of the Public Health Service," the CDC Director exercises authority that by law belongs to the Secretary that the Secretary has delegated to the CDC Director. Reorganization Plan No.3 of 1966 § 1, 5 U.S.C. app. 1. The CDC Director is appointed by the Secretary as a "non-career [Senior Executive Service ("SES")]" officer. *See* APP 037-038, Declaration of Julia M.C. LeFevre, PhD. ("LeFevre Decl.") ¶¶ 4, 6, & 8; *see generally* 5 U.S.C. §§ 3132(a)(2) & (a)(7). As a non-career SES officer, the CDC Director is removable by the Secretary at will. *See* 5 U.S.C. § 7543; *see also* 5 C.F.R. § 317.605(b).

3. The Health Resources and Services Administration

HRSA does not have "members." *Cf.* Br. in Supp. of Pls.' Mot. for Summ. J. ("Mot.") at 12, ECF No. 45. Like the CDC, HRSA is an agency of the Public Health Service and component of HHS. *See infra* note 26. It is led by an Administrator, who, like the CDC Director, is a non-career SES official appointed by the Secretary and removable by the Secretary at will. *See* APP 037-038, LeFevre Decl. ¶¶ 4, 6, & 7; 5 U.S.C. § 7543; *see also* 5 C.F.R. § 317.605(b). Present-day HRSA has evolved from several predecessor agencies through a number of departmental reorganizations over time as the Secretary has exercised authority over the Public Health Service.

Under section 1 of Reorganization Plan No. 3 of 1966, "all functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all other officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service" were transferred to the Secretary of Health, Education, and Welfare (later redesignated as the Secretary of Health and Human Services). Reorganization Plan No.3 of 1966 § 1, 5 U.S.C. app. 1.[1] HRSA was created by the Secretary in 1982 out of predecessor agencies within the Public Health Service. *See* 47 Fed. Reg. 38409 (Aug. 31, 1982).

The guidelines supported by HRSA under section 42 U.S.C. § 300gg-13(a)(4), pertaining to women, were developed pursuant to the Preventive Services Provision by the Institute of Medicine,[2] and subsequently accepted by HRSA.[3] *See* 75 Fed. Reg. 41,726, 41,728 (July 19, 2010) ("The Department of HHS is developing these guidelines and expects to issue them no later than August 1, 2011."). The guidelines referenced in subection (a)(3), pertaining to infants, children, and adolescents, were already in existence at the time the Preventive Services Provision was enacted. *See generally id.* at 41,740 *et seq.* (charts reflecting then-in-effect "[c]omprehensive guidelines for infants, children, and adolescents supported by HRSA"). A specific recommendation or guideline that is part of the comprehensive guidelines supported by HRSA pursuant to the Preventive Services Provision is "considered issued [for purposes of that provision]

[1] Reorganization Plan No. 3 of 1966, relating to the organization and functions of the Public Health Service, was "[p]repared by the President and transmitted to the Senate and the House of Representatives in Congress assembled, April 25, 1966, pursuant to the provisions of the Reorganization Act of 1949, 63 Stat. 203, as amended [*see* 5 U.S.C. § 901 *et seq*.]." It took effect upon publication in the Federal Register on June 25, 1966. *See* 31 Fed. Reg. 8855 (June 25, 1966). Congress expressly ratified the plan in 1984. *See* Pub. L. 98-532, 98 Stat. 2705 (Oct. 19, 1984).

[2] The Institute of Medicine (now called the National Academy of Medicine) serves as an independent, evidence-based scientific advisor with the goal of being "the most reliable source for credible scientific and policy advice on matters concerning human health." *See* Nat'l Acad. of Med., About the National Academy of Medicine, https://perma.cc/U7YH-VRFW.

[3] *See* HRSA, Women's Preventive Services Guidelines, Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being, https://perma.cc/VV4B-6BG6.

on the date on which it is accepted by the Administrator of HRSA, or if applicable, adopted by the Secretary of HHS." 80 Fed. Reg. 41,318, 41,322 (July 14, 2015).

4. The Coverage Requirement for PrEP Medications

Over 1 million people in the United States currently live with HIV, the virus that causes AIDS, a condition that has killed more than 700,000 people in the United States since 1981. Declaration of Dr. Demetre C. Daskalakis ¶ 4, APP 380. Despite improved treatments since it was first identified, HIV infection continues to spread and kill. In 2017, over 38,000 new HIV cases were diagnosed in the United States, and nearly 16,000 people with HIV died in the United States and its territories in 2019. *Id.*

PrEP medications are antiviral medications that can prevent individuals taking them from becoming infected with HIV. APP 381, *id.* ¶ 5. PrEP is highly effective at preventing the transmission of HIV, reducing the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%. *Id.* ¶ 7.

In 2019, the PSTF issued an "A" recommendation for PrEP medications for certain individuals, which resulted, by operation of 42 U.S.C. § 300gg-13(a)(1), in a requirement that health insurance[4] plans subject to the Preventive Services Provision provide coverage for PrEP medications without cost sharing. *See* APP 382, *id.* ¶ 10. By operation of the statute and implementing regulations, the PrEP coverage requirement took effect for plan years (or policy years) that began one year after the recommendation was issued, *i.e.*, one year after June 30, 2019. 42 U.S.C. § 300gg-13(b)(1); 45 C.F.R. § 147.130(b)(1).

B. Litigation and Procedural Background

Plaintiffs are six individuals and two businesses that object to obtaining health insurance that covers certain preventive services required to be covered by the Preventive Services Provision. A smaller group of Plaintiffs initially brought a class action complaint asserting eight claims and challenging the coverage of various services required by the Preventive Services Provision. *See*

[4] Throughout this brief, references to "health insurance" also include self-insured plans.

Compl., ECF No. 1. In lieu of opposing Defendants' motion to dismiss, *see* ECF No. 12, Plaintiffs amended their complaint to withdraw three claims and the putative class action status of the case, to add additional plaintiffs, and to limit the scope of preventive service requirements challenged to just two: contraception and PrEP. *See, e.g.*, First Amend. Compl. ("FAC") ¶¶ 108-111, ECF No. 14 (RFRA claim limited to challenging PrEP coverage), *id.* ¶¶ 21-28 (contraception coverage related allegations); *id.* ¶¶ 29-31 (PrEP coverage related allegations); *see generally id.*

The First Amended Complaint ("FAC") thus asserted five claims: challenges to sections (a)(1) through (a)(4) of the Preventive Services Provision under the Appointments Clause and the nondelegation doctrine, *see id.* ¶¶ 66-89; to section (a)(1) under the Vesting Clause, *see id.* ¶¶ 90-95; to the PrEP coverage requirement under the Religious Freedom Restoration Act ("RFRA"), *see id.* ¶¶ 108-111; and to preventive services coverage requirements added after 2010, as a matter of statutory interpretation, *see id.* ¶¶ 96-107.

Defendants moved to dismiss. *See* Mot. To Dismiss, ECF No. 20. After considering the parties' briefing, the Court granted Defendants' motion to dismiss in part. The Court dismissed Plaintiffs' statutory interpretation claims and dismissed the claims of the plaintiffs who asserted religious objections to the contraceptive coverage requirement as *res judicata*. *See* Order, ECF No. 35 at 1. The Court denied Defendants' motion to dismiss in all other respects. *Id.* Two Plaintiffs subsequently withdrew their claims voluntarily. *See* Jt. Stip. of Dismissal, ECF No. 47.

As to the remaining Plaintiffs and claims, four of the individuals (Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell) and both businesses assert religious objections to participating in health insurance plans that provide coverage for PrEP medications, *see* FAC, ¶¶ 36, 56, 63, while the remaining two individuals, Plaintiffs Joel Miller and Gregory Scheideman, have no religious objection to participating in insurance plans that cover certain preventive services but claim that they "do not want or need" such coverage. *Id.* ¶ 46, *see id.* ¶ 50. All Plaintiffs allege that the inclusion of coverage for the specific preventive services to which they object makes their insurance plans more expensive.

LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "'A dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Dyer v. Houston*, 964 F.3d 374, 379 (5th Cir. 2020) (quoting *Westfall v. Luna*, 903 F.3d 534, 546 (5th Cir. 2018)). "A fact 'is material if its resolution could affect the outcome of the action.'" *Id.* at 379-80 (quoting *Sierra Club, Inc. v. Sandy Creek Energy Associates, L.P.*, 627 F.3d 134, 134 (5th Cir. 2010)).

ARGUMENT

I. PLAINTIFFS LACK STANDING TO CHALLENGE THE PREVENTIVE SERVICES PROVISION

Although this Court held that Plaintiffs had sufficiently *alleged* the requirements of Article III standing to survive a motion to dismiss, Plaintiffs can no longer sustain their claims on the basis of mere allegations. Instead, at summary judgment, Plaintiffs must "'set forth' by affidavit or other evidence 'specific facts'" that support their standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (holding that "mere allegations" supporting standing are insufficient at summary judgment) (quoting Fed. R. Civ. P. 56(e)); *see also Ford v. NYLCare Health Plans of Gulf Coast, Inc.*, 301 F.3d 329, 334 (5th Cir. 2002). And, as at any other stage of litigation, it is the burden of the party invoking federal jurisdiction—here, Plaintiffs—to prove the existence of Article III standing. *Id.* To meet their burden, Plaintiffs must establish three elements: "(1) an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent; (2) a causal connection between the injury and the conduct complained of; and (3) the likelihood that a favorable decision will redress the injury." *Croft v. Governor of Tex.*, 562 F.3d 735, 745 (5th Cir. 2009).

For purposes of standing, there are essentially two theories of injury in this lawsuit. First, there are the religious objections that several Plaintiffs raise with respect to the PrEP coverage

requirement.[5] Their theory of injury is that, by paying premiums for health insurance that covers PrEP medications without cost-sharing, Plaintiffs are being forced to subsidize behavior to which they have a religious objection. *See* FAC ¶ 36; Mot. at 31 ("The compulsory coverage of PrEP drugs … compels [Plaintiffs] to choose between subsidizing lifestyles that violate their religious beliefs and [forgoing] health insurance entirely."). Second, all Plaintiffs raise non-religious objections to coverage for a number of preventive services on the basis that they do not want or need the coverage. Plaintiffs assert that their inability to purchase plans that exclude this coverage is itself an injury, and also that Plaintiffs suffer injury because health plans excluding such coverage would have lower premiums. *See, e.g., id.* at 9–10.

Plaintiffs lack standing on the basis of either theory of injury. The Plaintiffs raising economic objections have not shown (and cannot show) that their premiums or the premiums available to them have increased, that any increase in costs was caused by the Preventive Services Provision, or that a favorable ruling will cause insurers to offer plans that exclude Plaintiffs' undesired coverage or have lower premiums because of any such exclusion. The religious-objector Plaintiffs lack standing because they have not shown that the ACA caused their issuers to include PrEP medications in Plaintiffs' health plans.

A. The Economic Objectors Cannot Show Injury, Causation, or Traceability

For Plaintiffs to have standing, they need to produce evidence showing that they have suffered the economic harm alleged and that the economic harm was in fact caused by the particular practice or provision being challenged, as well as showing that the relief sought will redress the particular harm at issue. The Fifth Circuit applied the same requirement in *Ford*, 301 F.3d at 333. There, the plaintiff was a surgeon who claimed that HMOs were falsely advertising to patients about the merits of the HMOs' practices, and that the false advertising gave the HMOs sufficient market power to impose cost-control measures on the plaintiff that reduced his income.

[5] Plaintiffs also raised religious objections to the contraceptive coverage requirement, but this Court ruled that *res judicata* barred those claims.

The Fifth Circuit entered summary judgment against the doctor, holding that, "[t]o meet the causation requirement, [he] would have to present evidence affirmatively proving that the reduction in his income was a consequence of the HMO's' restrictive policies," and that "those policies in turn were established or at least made more onerous as a result of increased market power created by the acquisition of new customers through the defendants' allegedly deceptive ads." *Id.* at 333. *Ford* emphasizes that a party claiming economic injury from the defendant's actions must show economic damage that is attributable to the particular practice claimed to be unlawful.

1. The Economic-Objector Plaintiffs Cannot Show Injury-in-Fact

The first deficiency for Plaintiffs is that they cannot show they suffered a legally cognizable injury arising from the Preventive Services Provision. The only alleged harm the economic-objector Plaintiffs have asserted is that the Preventive Services Provision led them to pay higher premiums than would otherwise be available if Plaintiffs could obtain health plans that exclude their unwanted coverage. That is the standing theory Plaintiffs have advanced throughout this litigation, and the theory on which this Court relied in denying Defendants' motion to dismiss. *See* Order on Mot. to Dismiss at 11, ECF No. 35 ("[T]he free-market Plaintiffs object to paying higher prices for health insurance that provides coverage they do not wish to purchase."); *see also, e.g.*, FAC ¶ 35 ("The defendants' enforcement of 42 U.S.C. § 300gg-13, however, makes it impossible for [Kelley, Starnes, and the Maxwells] to purchase less expensive health insurance that excludes this unwanted coverage, thereby inflicting injury in fact."). For that reason, to demonstrate standing at the summary judgment stage, Plaintiffs need to show that the Preventive Services Provision in fact increases their premiums, or, at the very least, that the premiums available to them have increased as compared to the premiums that would be available to them in the absence of those statutory provisions.

The record is devoid of any such evidence. Plaintiffs' brief states without further elaboration that the Preventive Services Provision "prevent[s] insurers from competing with each other by offering policies that shift the costs of preventive care to beneficiaries in exchange for

lower premiums." Mot. at 10. For factual support, they cite their own declarations, which assert a desire to have the option of selecting a plan without the challenged coverage. But those declarations do not show, or even purport to show, that Plaintiffs' premiums have increased. No Plaintiff's declaration gives any evidence that the Preventive Services Provision has increased their premiums, nor any evidence from which such a conclusion could even be inferred. Plaintiffs have therefore failed entirely to "'set forth' by affidavit or other evidence 'specific facts'" to show standing. *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)).

At times in their Motion, Plaintiffs appear to argue that, in addition to being harmed by allegedly higher premiums, they are also harmed merely by the restriction on what coverage terms can be offered to them, without a showing that the restriction further harms them. *See* Mot. at 9. But without showing higher premiums or some other way that the limitation translates to a negative effect on them, they have not shown they have been *injured* by the provision of extra coverage they do not need or want. They have identified no harm they suffer merely by having such unwanted coverage, or even harm suffered by their premiums being pooled with others to offset risks that Plaintiffs do not face. To the extent Plaintiffs bring this lawsuit merely to vindicate an abstract right to an insurance market with fewer restrictions on the types of plans offered, they have not identified any basis for the existence of such an intangible right, let alone a way in which its invasion harms them. *See, e.g.*, *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204–05 (2021) (intangible harms require some basis, such as "injuries with a close relationship to harms traditionally recognized as providing a basis for lawsuits in American courts") (citation omitted).

2. The Economic-Objector Plaintiffs Cannot Show Causation

Because Plaintiffs have failed to prove an increase in premiums, they have necessarily failed to show that any increase in their premiums would be attributable to the preventive-care coverage requirements. To show causation, they would need to establish that the purported economic injury was "a consequence" of the allegedly wrongful conduct—here, the requirement under the Preventive Services Provision to include a challenged service in their health plans. *Ford*, 301 F.3d at 333. Yet Plaintiffs never assert, and could not establish with admissible evidence, that

their health insurance premiums would have stayed the same price over the past twelve years if not for the Preventive Services Requirement.

Rather than produce any evidence of causation, Plaintiffs admitted during discovery that they could not quantify the effect that any of the preventive-care coverages had on their premiums. For each of the coverages to which Plaintiffs stated an objection, Defendants asked each Plaintiff to admit they could not quantify the impact of that coverage requirement on their health insurance premiums, and to admit they had "no knowledge" of whether that coverage had any impact on their premiums independent of any other preventive care requirement. Braidwood and the Maxwells stated for each RFA that they "lack sufficient knowledge and information to admit or deny this Request." *See* APP 167-178, Nos. 1–46; APP 225-236, Nos. 1–48. In other words, they disclaimed any knowledge about any effect of the challenged provisions on their premiums. The other Plaintiffs made the same response, but added the conclusory boilerplate statement that their health insurance premiums increased "after the coverage requirements under 42 U.S.C. § 300gg-13 were collectively mandated, including the mandate specified" in each RFA. APP 261-273, Nos. 1–44; APP 206-220, Nos. 1–48; APP 279-294, Nos. 1–48; APP 242-256, Nos. 1–48; APP 183-200, Nos. 1–56. But the mere fact that Plaintiffs' insurance premiums increased *after* the coverage requirements of the Affordable Care Act were adopted does not establish that they increased *because* of those provisions. Thus, these Plaintiffs also admitted that they lack any knowledge of the effect of the Preventive Services Provision on their premiums, and they provided no other factual support that their premiums increased in the past twelve years.

Even if they had introduced evidence that premiums went up after the passage of the ACA or after the effective date of particular preventive-care coverage requirements, Plaintiffs would still need to show that those changes were attributable to the specific preventive-care coverage requirements to which they object, and not to some other provisions of the law or to events unrelated to the law, just as the plaintiff in *Ford* needed to show that his income "declined … more than would be expected as a result of events completely unrelated to the HMO's activities." 301 F.3d at 333. Plaintiffs have not made that showing. They cannot sustain their burden by providing

a single sentence of speculation that the absence of the Preventive Services Provision would lead to lower premiums as a result of price competition.

The only purported evidence of causation Plaintiffs provide is a lay declaration of Michael F. Cannon, which attempts to do the work of an expert declaration, although the declarant filed no expert witness report and does not disclose his qualifications or the basis for his conclusions.[6] For that reason, this Court should decline to consider his declaration, which offers an unadorned lay opinion apparently based entirely on public records. *See Mississippi Chem. Corp. v. Dresser-Rand Co.*, 287 F.3d 359, 373 (5th Cir. 2002) (a lay opinion witness "must have personalized knowledge of the facts underlying the opinion and the opinion must have a rational connection to those facts").

In addition to being procedurally deficient as an expert declaration, the declaration is also substantively deficient. Although Plaintiffs must show that the Preventive Services Provision increased their premiums and that a favorable ruling in this litigation would lead to plans that offer lower premiums in exchange for forgoing the coverages of the Preventive Services Provision, the declarant makes no representations regarding premiums or how the Preventive Services Provision affects those premiums. Instead, the declarant asserts that "[t]he evidence from the pre-Affordable Care Act individual market and from the short-term, limited duration insurance market shows that when the government leaves them free to do so, insurers offer health plans that exclude or limit coverage of preventive care, including contraceptives, and that consumers purchase those plans." App'x to Pls.' Mot. for Summ. J. ("Pls.' App'x") at 75, ECF No. 46. But the declaration does not contain any information about premiums, which is the basis for Plaintiffs' alleged injury. The availability of plans without particular coverage does not establish that such plans would be cheaper, nor does it establish a causal relationship or show redressability.

[6] Indeed, per the parties' proposal, *see* Joint Status Report re: Schedule, ECF No. 39, the Scheduling Order provided Plaintiffs a deadline of May 1, 2021 to serve an expert report. *See* Scheduling Order, ECF No. 40. They failed to do so, and indeed never provided one in this case. Their attempt to cure this error and evade the obligations of expert discovery through their deficient lay declaration should not be countenanced, and—although it cannot support Plaintiffs' standing for the reasons explained herein—the Court should decline to consider this evidence.

In arguing that issuers would offer plans that omit the challenged coverage if not for the ACA, Cannon's seven-paragraph declaration relies on two public documents. First, he cites two paragraphs from an interim final rule, which stated that "many health plans [at the time] already cover[ed] preventive services" but that the terms of those plans varied. *Id.* at 74. That quote does nothing to establish that the Preventive Services Provision has led to an increase in premiums for the plans available to Plaintiffs.

Second, the declarant cites to a Democratic Staff Report from June 2020 that examines certain Short-Term Limited-Duration Health Insurance ("STLDI") plans. *See id.* at 75, 115. STLDI plans are health insurance plans that have an initial contract term of less than one year, are limited to a maximum duration of three years including renewals, and are exempted from most federal health insurance regulations, including parts of the ACA. *Ass'n for Cmty. Affiliated Plans v. United States Dep't of the Treasury*, 966 F.3d 782, 784 (D.C. Cir. 2020). But STLDI plans are not exempt just from the Preventive Services Provision; they are radically different from most ACA-compliant plans. STLDI plans "can be purchased at a fraction of the cost because they are exempt from the ACA's community-rating, guaranteed-issue, and essential-health-benefits requirements." *Id.* at 786. Plaintiffs' declarant cites to a portion of the Democratic Staff Report that says a number of STLDI plans exclude coverage of contraceptives and other preventive care. The desired implication appears to be that, because some STLDI plans exclude preventive coverage, insurers would also choose to offer non-STLDI plans that exclude the same preventive coverage if not for the ACA, and that the premiums would be cheaper for Plaintiffs. But Plaintiffs and their lay declarant provide no evidentiary basis for this inferential leap—for example, they provide no evidence that STLDI plans with lower premiums owe those lower premiums to the inapplicability of the Preventive Services Provision, as opposed to the inapplicability of community rating, guaranteed issue, and essential-health-benefits requirements. *Id.*

In short, Plaintiffs and their declarant do nothing more than show that certain health plans under different legal regimes—different in many more ways than just their exclusion from the ACA's preventive-care requirements—do not or did not uniformly cover preventive services on

the same terms as one another. Plaintiffs and their declarant leave out any discussion of premiums, let alone an evidentiary showing that the preventive-care requirements have caused Plaintiffs' available insurance plans to have higher premiums than they otherwise would. For these reasons too, Plaintiffs have failed to establish standing.

3. The Economic-Objector Plaintiffs Cannot Show Redressability

The economic-objector Plaintiffs also cannot show redressability. Their theory of redressability rests on the speculative assumption that, if the Preventive Services Provision was held unlawful, insurance companies would respond by "competing with each other by offering policies that shift the costs of preventive care to beneficiaries in exchange for lower premiums." Mot. at 10.

But the Supreme Court has made clear that "much more is needed" when the "plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*," because then the plaintiff's theory of standing will "hinge on the response of the regulated (or regulable) third party to the government action or inaction." *Lujan*, 504 U.S. at 562 If a regulated entity, such as the insurance companies offering these plans, can exercise "broad and legitimate discretion," it is Plaintiffs' burden to "adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id.*; *see also Inclusive Communities Project, Inc. v. Dep't of Treasur*y, 946 F.3d 649, 657 (5th Cir. 2019) (where it is "unclear what effect" the desired relief would have on the conduct of the entities allegedly harming the plaintiffs, it's "similarly uncertain that granting" the desired relief "would remedy [the plaintiff's] injuries").

Here, Plaintiffs have provided no factual basis for concluding that enjoining the Preventive Services Provision would lead to lower premiums. Insurance issuers possess broad discretion in building and pricing the plans they offer, and if this Court were to grant summary judgment to Plaintiffs and enter an injunction entitling them to purchase health plans that exclude the challenged coverage, the issuers might make a variety of choices that would not yield lower premiums for Plaintiffs. Even in the absence of the Preventive Services Provision, they could

determine that there is not a sufficient market for plans that exclude coverage to which Plaintiffs object. Or issuers could choose to retain the coverages but to change the cost and payment structures for those plans in ways other than by changing premiums, which would raise the question whether Plaintiffs would be affected by whatever particular methods the insurers chose to offset their costs. Or they could determine that preventive services reduce the insurer's costs by forestalling more expensive remedial services, thereby justifying lower premiums for plans that *include* the challenged coverage. *See* 75 Fed. Reg. at 41,731, 41,733 (noting that "some of the benefits of preventive services accrue to society as a whole" and that "some of the recommended preventive services will result in savings due to lower healthcare costs"). In short, Plaintiffs have merely offered speculation about the effect of enjoining this provision of the ACA, and that is insufficient at this stage of proceedings, especially where that speculation relies on guesswork by a lay witness about what third-party insurers might do.

Plaintiffs also cannot establish redressability because a favorable ruling on their claims would still leave many of the challenged coverages in place. The economic-objector Plaintiffs do not contest that Congress has the authority to pass a law requiring insurers to cover particular services on the terms at issue here. Instead, Plaintiffs challenge only the mechanisms Congress can put into place for those coverage requirements to be newly determined or updated by entities other than Congress—they challenge the appointment procedures for the relevant officials, and whether the entities have been given enough guidance in exercising their discretion. But as Plaintiffs themselves acknowledged earlier in this lawsuit, their challenges to those procedures would not call into question the coverage requirements for PSTF and ACIP recommendations that existed at the time of the ACA's passage. FAC ¶¶ 97–98, 100–01, 103–04, 106–07. To the contrary, Plaintiffs have requested this Court to "enjoin the defendants from enforcing any coverage mandate based upon an agency rating, recommendation, or guideline that issued after March 23, 2010." FAC ¶ 112(e). And so, even if Plaintiffs prevail on their Appointments Clause and nondelegation challenges, their health plans would still be required to cover PSTF

recommendations that had an A or B grade when the ACA was enacted, and any ACIP immunization recommendations that existed at the time.

Plaintiffs make no effort to address this serious redressability problem. For example, the only ACIP immunization any Plaintiff complains about is the requirement for coverage of the HPV vaccine. Pls.' App'x 35, ¶ 8; Pls.' App'x 41, ¶ 8; Pls.' App'x 47, ¶ 10; Pls.' App'x 52, ¶ 8; Pls.' App'x 58, ¶ 8; Pls.' App'x 64, ¶ 8; Pls.' App'x 69, ¶ 11. But ACIP had a recommendation in place for the HPV vaccine since 2007, before the ACA was enacted, although the scope of the recommendation was different.[7] So, even if the economic-objector Plaintiffs prevailed on all of their claims, their insurance plans would still need to cover the HPV vaccine, meaning that Plaintiffs cannot show a victory on their Appointments Clause or nondelegation claims will permit insurers to lower premiums in exchange for not covering the HPV vaccine.

And the same is true for almost all of the PSTF coverages to which Plaintiffs object. Even if the specifics of the recommendations would change—for example, the particular populations for which a screening or intervention is necessary—Plaintiffs' insurance plans would still have to cover some form of almost every preventive service Plaintiffs categorically claim neither to need nor to want. The PSTF in 2009 gave an "A" grade to counseling and interventions for tobacco use.[8] And a "B" grade in 2003 to behavioral interventions for obesity.[9] And a "B" grade in 2004 to screening and counseling for alcohol misuse.[10] And a "B" grade in 2003 for behavioral dietary

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[7] *See* CDC, Human Papillomavirus (HPV) ACIP Vaccine Recommendations, https://perma.cc/XGN6-UDP5.

[8] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Tobacco Use in Adults and Pregnant Women: Counseling and Interventions (Apr. 15, 2009), https://perma.cc/D37Z-H93C.

[9] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Obesity in Adults: Screening and Counseling, 2003 (Nov. 3, 2003), https://perma.cc/4FW6-83TK.

[10] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Alcohol Misuse: Screening and Counseling, 2004 (Apr. 6, 2004), https://perma.cc/6DFZ-CLS6.

counseling.[11] And an "A" or "B" grade in 2007 for certain chlamydia screenings.[12] And an "A" or "B" grade in 2005 for certain gonorrhea screening.[13] And an "A" grade in 2009 for hepatitis B screening for pregnant women.[14] And a grade of "A" in 2005 for HIV screenings in pregnant women and individuals at increased risk.[15] And a grade of "B" in January 2010 for obesity screening in children.[16] And a grade of "B" in 2008 for screening for sexually transmitted infections in sexually active adolescents and adults at increased risk.[17] And a grade of "A" in 2004 for syphilis screening.[18] Indeed, it appears that the only categories of PSTF recommendations to which Plaintiffs object that did not have an "A" or "B" grade at the time of the ACA's passage are hepatitis C screening, lung cancer screenings for current and former smokers, PrEP drugs, and screening for unhealthy drug use. So, rather than claiming they would be free of the PSTF's recommendations with a victory in this case, Plaintiffs instead need to show that they have standing based on a reversion to earlier versions of the PSTF recommendations for most of their objections. And since Plaintiffs have failed to show standing for their challenge in its entirety, they especially cannot show injury, causation, and redressability for those particular changes.

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[11] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Healthy Diet: Behavioral Counseling in Primary Care, January 2003 (June 15, 2003), https://perma.cc/V6DX-NXWX.

[12] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Chlamydial Infection: Screening (June15, 2007), https://perma.cc/V8YS-RJL7.

[13] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Gonorrhea: Screening (May 15, 2005), https://perma.cc/33QC-ED6W.

[14] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Hepatitis B in Pregnant Women: Screening (June 15, 2009), https://perma.cc/5TNC-ARM8.

[15] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Human Immunodeficiency Virus (HIV) Infection: Screening, 2005 (July 5, 2005), https://perma.cc/FVU3-TCZK.

[16] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Obesity in Children and Adolescents: Screening, (Jan. 15, 2010), https://perma.cc/9S7H-ASSG.

[17] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Sexually Transmitted Infections: Behavioral Counseling (Oct. 15, 2008), https://perma.cc/X37E-U7ZL.

[18] U.S. Preventative Servs. Task Force, Final Recommendation Statement, Syphilis Infection: Screening (July 15, 2004), .https://perma.cc/FN4F-LVPC.

In sum, the economic-objector Plaintiffs contend that they are suffering higher premiums as a result of the Preventive Services Provision. But they provide no evidence showing that their premiums or available premiums have increased, that such an increase is attributable to the requirements that insurers cover the particular services to which Plaintiffs object, or that insurers will respond to a favorable ruling by offering lower premiums in exchange for Plaintiffs' surrendering the unwanted coverages. Because Plaintiffs have failed to present any evidence to meet their burden at summary judgment to show injury, causation, and redressability, judgment must be entered against them.

B. The Religious Objectors to the PrEP Coverage Requirement Cannot Show Causation or Redressability

Although Plaintiffs purport to raise religious objections to a number of coverage requirements in their summary-judgment briefing, they have previously limited their religious objections to only two preventive-care coverage requirements: PrEP medications and contraceptive coverage, the latter of which has been dismissed on the basis of *res judicata*. Plaintiffs cannot now amend their claims to raise religious challenges to other coverage requirements under the ACA. *See, e.g.*, *Fisher v. Metro. Life Ins. Co.*, 895 F.2d 1073, 1078 (5th Cir. 1990) (a claim not "raised in [the plaintiff's] … complaint … was not properly before the court"); *Jackson v. Gautreaux*, 3 F.4th 182, 189 (5th Cir. 2021) (a plaintiff who switches the theory of his claim at summary judgment is attempting "precisely the sort of surprise switcheroo that our precedents forbid"). In considering whether Plaintiffs' purported religious injury confers standing, this Court should consider only that alleged injury for the challenge to the PrEP coverage requirement.

Although the religious-objector plaintiffs' affidavits now claim religious objections to other coverage requirements, their religious objections in their Complaint were expressly limited to the requirements to cover PrEP medications and contraception. *See* FAC ¶ 36 ("Mr. Kelley, Mr. Starnes, Mr. Maxwell, and Ms. Maxwell also object to contraceptive coverage and the coverage of PrEP drugs on religious grounds."); ¶¶ 62–63 ("Dr. Hotze is a Christian, and he operates his

business according to Christian principles and teaching. Dr. Hotze is therefore unwilling to allow Braidwood's self-insured plan to cover PrEP drugs such as Truvada and Descovy because these drugs facilitate or encourage homosexual behavior, which is contrary to Dr. Hotze's sincere religious beliefs."). The religious objectors' complaints regarding other coverage requirements were stated separately and based solely on the grounds that Plaintiffs did "not need or want" that coverage for non-religious reasons—for example, that they did not want or need STD testing "because they are in monogamous relationships with their respective spouses." *Id.* ¶ 35. The First Amended Complaint expressly made religious objections to contraceptive coverage and PrEP, and expressly distinguished those alleged injuries from Plaintiffs' objections that were based merely on not needing or wanting certain coverage. That appears to be how this Court understood the categories of alleged injuries as well, stating in its disposition of the motion to dismiss that the challenges to coverage other than contraception and PrEP medications were based on Plaintiffs' objection to coverage they "do not want or need" and for which the alleged injury is "more expensive health insurance plans." Order on Mot. to Dismiss at 12. Having limited their religious objections in the Complaint to contraceptives and PrEP, Plaintiffs cannot now raise religious objections to new forms of coverage.

As to PrEP, the religious-objector Plaintiffs cannot show that their alleged injury is traceable to the Preventive Services Provision. Although the ACA requires most health insurance plans to cover PrEP, that does not mean the presence of such coverage in Plaintiffs' health plans is caused by that requirement. That is because Plaintiffs have not provided factual evidence showing that, but for the Preventive Services Provision, their insurance plans would omit PrEP coverage. Because it is Plaintiffs' burden to prove standing by competent evidence, their claims must be denied for lack of standing.

The religious-objector Plaintiffs' discovery responses disclaim any knowledge regarding whether their health plans covered PrEP before the coverage requirement took effect, making it entirely a matter of speculation whether it is the Preventive Services Provision that caused their health plans to cover PrEP medications. The Maxwells attested that each of them had health

insurance several times prior to the 2021 effective date of the PrEP coverage requirement. APP 397, No. 4(a). But when asked whether any of those plans had covered PrEP drugs, Plaintiffs offered only a guess: "To the best of our knowledge, none of the health-insurance plans in which we have enrolled included coverage of PrEP drugs, because the mandate to cover PrEP drugs as preventive care did not take effect until 2021." In other words, Plaintiffs merely assume that their past health plans did not cover PrEP drugs because the coverage was not required by the ACA. But an unadorned assumption is not sufficient to establish standing at summary judgment. And when asked what efforts since January 1, 2000, they had made to "obtain health insurance that does not include coverage" of PrEP drugs, the Maxwells admitted that they "did not make efforts . . . to obtain health insurance that does not include coverage of PrEP drugs." APP 399, No. 5. In short, the Maxwells have presented no competent evidence that they would have a plan without PrEP coverage but for the ACA requirement.[19] And this Court should not assume, as Plaintiffs do, that a health plan will necessarily lack PrEP coverage absent the 2020 coverage requirement. As the Declaration of Lourdes Grindal Miller shows, all issuers of Qualified Health Plans in the federally facilitated exchanges in Texas issued public data showing that they covered both FDA-approved PrEP medications in 2019, before the PrEP coverage requirement took effect. APP 452-53 (Miller Decl.).

None of the individual religious-objector Plaintiffs is able to say that they previously lacked PrEP coverage or tried to avoid PrEP coverage, depriving them of any basis to claim causation. And although Plaintiffs' religious-objection claims should be limited only to the PrEP coverage requirement as discussed above, this deficiency is also true for all of the coverages for which Plaintiffs attempt to belatedly raise a religious challenge.

[19] The discovery responses of Kelley are a carbon copy of the Maxwells'. Kelley likewise states his guess that his prior insurance did not include PrEP coverage, APP 302, No. 4(d), and he likewise admits that he made no effort to find insurance that did not cover PrEP drugs. APP 302-03, No. 5. The same is true of Starnes' responses. APP 339, Nos. 4(d), 5.

Only Braidwood asserts without qualification that it did not provide coverage for PrEP prior to the PrEP coverage requirement. *See* APP 408, No. 4(e). Although Braidwood must cover PrEP as part of its health plan, its status as a self-insured entity means that Braidwood cannot yet show standing to challenge the coverage requirement. Braidwood self-insures and thus does not pool risk with other insureds, instead paying out claims itself, so Braidwood does not contribute financially to off-setting the risk of any insureds outside of its own employees. Braidwood therefore does not pay to offset the risk of future claims for PrEP, but instead merely bears the risk itself that a claim for PrEP may one day be filed and that Braidwood will then have to pay it. Yet Braidwood has presented no evidence that it has been required to make any payment related to PrEP so far. Braidwood therefore cannot sustain this case on the hypothetical possibility that it may one day have to make a payment towards PrEP treatment, without any evidence that such an event will or likely will happen. Until then, as a self-insured plan, Braidwood operates only under a legal obligation to cover PrEP if such a claim is submitted, and an abstract legal obligation is insufficient to establish standing. *See Barber v. Bryant*, 860 F.3d 345, 357 (5th Cir. 2017) ("An injury that is based on a 'speculative chain of possibilities' does not confer Article III standing." (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013))).

Additionally, the religious-objector Plaintiffs have not shown that a ruling in their favor will redress their alleged injuries. As with the economic-objector Plaintiffs, the religious-objector Plaintiffs have provided no evidence showing that insurers will choose to offer plans without PrEP coverage if permitted, and no evidence that the hypothetical PrEP-free plans will be offered on terms that make them sufficiently desirable that Plaintiffs will choose to purchase those plans. For that reason, Plaintiffs have not shown that a favorable ruling is likely to give them relief from the alleged harm of having their plans cover PrEP.

Indeed, Plaintiffs' own allegations in this litigation undermine any argument that an injunction in favor of religious objectors would redress their injuries. Initially, the religious-objector plaintiffs sought to challenge the contraceptive coverage requirement as well. FAC ¶ 37. But those plaintiffs were protected by an injunction that permitted insurers to provide health

insurance for religious objectors that did not include contraceptive coverage. *DeOtte v. Azar*, 393 F. Supp. 3d 490, 514–15 (N.D. Tex. 2019); FAC ¶ 28. Those religious-objector Plaintiffs argued that the *DeOtte* injunction provided no real relief, because insurers were uninterested in offering plans that were available only to the subset of consumers with religious objections protected by an injunction. FAC ¶ 28 ("few if any insurance companies are offering health insurance" that excludes abortifacient contraception); Opp'n to Defs.' Mot. to Dismiss 5, ECF No. 24 ("It is not at all surprising that insurers are slow to create new policies that can only be offered or sold to a narrow slice of the population."). Yet Plaintiffs now contend that a ruling for the religious objectors on the PrEP coverage requirements will give them the ability to obtain their preferred coverage. That inconsistency should prove fatal to Plaintiffs' theory of redressability.

In short, the individual religious objectors cannot show that the ACA caused their issuers to provide PrEP coverage, and they cannot show that they will be able to obtain the health plan they want even with a favorable ruling. And for Braidwood, although it has attested during discovery that it did not previously cover PrEP for its employees as part of its self-insured plan, it has not shown that its obligation to cover PrEP has or will translate into any payments for PrEP treatment. For those reasons, Plaintiffs cannot demonstrate standing for their religious-objection claims.

C. Plaintiffs Kelley, Kelley Orthodontics, and Starnes Cannot Show Standing Because They Do Not Provide or Purchase Health Insurance

During discovery, Plaintiffs Kelley, Kelley Orthodontics, and Starnes revealed another reason they cannot show standing—Kelley and Starnes state that they participate in "Christian bill-sharing," which is not insurance and thus is not subject to the ACA's preventive-coverage requirements, while Kelley Orthodontics does not provide health insurance to its employees at all. These Plaintiffs cannot show that they are harmed by the regulation of products they choose not to purchase or provide, especially where they have presented no evidence showing an intent to enter that market. *See Lujan*, 504 U.S. at 563–64 (rejecting plaintiffs' standing to challenge alleged harms to endangered species where the plaintiffs professed only "'some day' intentions" to visit

the endangered species at issue).

Plaintiff Kelley Orthodontics admitted during discovery that it has not provided health insurance to its employees since October 30, 2016. APP 417-18, No. 3(a). And Kelley Orthodontics does not claim that it stopped offering insurance because of the preventive-coverage provisions at issue in this case. Instead, it claims a variety of reasons for no longer offering health insurance: the premiums "had become too expensive," it was "being forced to pay for coverage that [Plaintiff Kelley] found objectionable" (although Kelley Orthodontics does not claim that the "objectionable" coverage is the same as at issue in this lawsuit), and several employees would become eligible for more desirable health insurance if Kelley Orthodontics stopped offering coverage. *Id.* And even that claim of multiple causes is of questionable veracity; in response to Defendants' Requests for Admission, Kelley Orthodontics volunteered that it had stopped providing health insurance in 2016 because "the premiums for health insurance that I provide for my employees increased, so much so that . . . I was forced to stop offering health insurance as a benefit because it was too expensive." APP 183-200, Nos. 1–56. Kelley Orthodontics has offered no evidentiary basis to conclude that the Preventive Services Provision caused it to stop purchasing health insurance—as discussed above, Plaintiffs have not shown that the Preventive Services Provision increased their premiums at all, let alone that the Preventive Services Provision so increased Kelley Orthodontics's premiums as to drive it out of the market entirely. And Kelley Orthodontics has not claimed, let alone proved, that it would switch back to providing insurance if the Preventive Services Provision were invalidated. Plaintiffs have provided no theory how Kelley Orthodontics is harmed by the regulation of a market that it chooses not to participate in, nor how a favorable ruling would redress any such harm.

The same is true for Plaintiffs Kelley and Starnes. Both state that they stopped purchasing health insurance in 2016 and currently use Christian bill-sharing. APP 339, No. 4(a); APP 301, No. 4(a). As with Kelley Orthodontics, Kelley and Starnes do not claim that the preventive-services provisions are keeping them from purchasing insurance, or that they would purchase insurance if the post-enactment PSTF, ACIP, and HRSA coverages were no longer required. In

fact, as with Kelley Orthodontics, both Kelley and Starnes admitted during discovery that they stopped purchasing health insurance and switched to Christian bill-sharing because their health insurance premiums increased. APP 206-220, Nos. 1–48; APP 279-294, Nos. 1–48. And as with Kelley Orthodontics, neither Kelley nor Starnes has shown that the premiums increased because of the Preventive Services Provision, nor that invalidating the Provision would reduce premiums enough to entice them back into the market for health insurance. In short, Kelley Orthodontics, Kelley, and Starnes are attempting to litigate the regulation of a market they have chosen not to participate in, without showing that the Preventive Services Provision has driven them out of or is keeping them from a market they would otherwise enter. For that reason, they can show none of the requirements of standing.

* * *

For all of the foregoing reasons, none of the Plaintiffs have satisfied their burden to establish they have standing to bring any of their claims. Accordingly, the case must be dismissed for lack of jurisdiction.

II. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' APPOINTMENTS CLAUSE AND VESTING CLAUSE CLAIMS

The Secretary of Health and Human Services has ratified the current guidelines subject to the Preventive Service Provision's coverage requirement, resolving any putative defect in the appointment of the entities who initially issued those guidelines or the vesting of their authority. But even if he had not, there is no defect in these entities' authority under the Appointments Clause or the Vesting Clause. Accordingly, judgment should be entered for Defendants on both Plaintiffs' Appointments Clause and Vesting Clause Claims.

A. The Secretary's Ratification of the Current Preventive Services Coverage Requirements Defeats Plaintiffs' Appointments Clause Claim

Because the Secretary of Health and Human Services, a duly appointed principal officer of the United States, has ratified the current recommendations and guidelines subject to the Preventive Services Provision's coverage requirements, Plaintiffs' Appointments Clause claim must fail. *See, e.g., Guedes*, 920 F.3d at 13. Plaintiffs' argument to the contrary—that the Secretary is not permitted to ratify these guidelines and recommendations—cannot be squared either with the structure of HHS or the traditional tools of statutory interpretation. But even if Plaintiffs were right, the remedy mandated by Supreme Court authority would not be to invalidate the preventive care coverage requirements as Plaintiffs ask, but to *permit* the Secretary to ratify the guidelines and recommendations to allow the statutory scheme to operate in a constitutional manner. *See, e.g., United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021). Either way, Defendants are entitled to judgment in their favor on Plaintiffs' Appointments Clause claim.

1. The Secretary Is a Constitutionally Appointed "Principal Officer" with Authority over the Whole of HHS Who Can Ratify the Work of Its Components

Plaintiffs claim that the Appointments Clause requires a principal officer of the United States to approve the recommendations and guidelines at issue for the preventive-care coverage requirements to be valid. While Defendants dispute this contention, the Secretary's January 21, 2022 ratification of all current recommendations and guidelines under the Preventive Services Provision resolves any putative defect in the authority of the entities who issued the recommendations and guidelines. *See* APP 002. And it addresses the key purpose of the Appointments Clause, by "guarantee[ing] accountability for the appointee's actions" and accepting them as the Secretary's own actions. *Arthrex, Inc.*, 141 S. Ct. at 1979.

"Regardless of whether" an initial decisionmaker "was or was not validly appointed under . . . the . . . Appointments Clause," "a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting a claim, resolves the claim on the merits by remedy[ing] [the] defect (if any) from the initial appointment." *Guedes*, 920 F.3d at 13 (internal

quotation marks and citations omitted); *accord Consumer Fin. Prot. Bureau v. Gordon*, 819 F.3d 1179, 1190-92 (9th Cir. 2016). Here, there is no dispute that Secretary Becerra was constitutionally appointed. It is a matter of public record that he was nominated by President Biden on January 20, 2021 and confirmed by the Senate on March 18, 2021.[20] This process is the most that the Appointments Clause can require. *See* U.S. Const. art. II § 2 cl. 2 (The President "shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . Officers of the United States."). Accordingly, even if it were necessary for a principal officer of the United States to approve the recommendations and guidelines addressed in the Preventive Services Provision, any possible defect in the appointments of other officials has been cured, and Plaintiffs' Appointments Clause claim must fail.

2. HRSA and the CDC (which ACIP Advises) Are Components of HHS that Exercise the Secretary's Power and Are under the Secretary's Control

Plaintiffs argue that Secretarial ratification is not permissible because the statute mentions both HRSA and ACIP by name, and because ACIP and HRSA are comprised of principal officers not supervised by others in the Department. Mot. at 19-20, 23-24. But Plaintiffs misread the Preventive Services Provision and their arguments suffer from a fundamental misunderstanding of these entities and the overall structure of HHS.

To be sure, the Preventive Services Provision refers to "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention" and "comprehensive guidelines supported by the Health Resources and Services Administration." 42 U.SC. § 300gg-13(a)(2)-(4). But Plaintiffs' argument ignores the identity and structure of ACIP and HRSA and their respective positions *within* the hierarchy of HHS. Because HRSA is an agency whose Administrator's responsibilities and duties are wholly subject to the control of the Secretary, and ACIP simply advises the CDC Director—

[20] *See* PN 78-2, 117th Cong. (2021), https://perma.cc/6QDC-39D4; U.S. Senate, Roll Call Vote 117th Congress – 1st Session, Roll Call Vote on the Nomination of Xavier Becerra, PN 78-2 (2021) https://perma.cc/4ABU-BBGX.

who in turn exercises authority delegated by and subject to the control of the HHS Secretary—the Secretary has the power to ratify any actions taken by his subordinates.

HRSA and CDC are federal agencies that are a part of the Public Health Service. *See* Public Health Service Act, Section 202 n.1.[21] Since 1966, "all functions of the Public Health Service, all . . . officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service" have resided in the Secretary, to be delegated as he or she sees fit. Reorganization Plan No. 3 of 1966, 5 U.S.C. app. 1; *see also* 42 U.S.C. § 202 ("The Public Health Service in the Department of Health and Human Services shall be administered by the Assistant Secretary for Health under the supervision and direction of the Secretary."). Because the Public Health Service is ultimately "under the supervision and direction of the Secretary," the Secretary has the final say over its actions and the actions of its officials. *See, e.g., Arthrex, Inc.*, 141 S. Ct. at 1983 ("'The power to superintend . . . must imply the right to judge and direct,' thereby insuring that 'the responsibility for a wrong construction rests with the head of the department when it proceeds from him.'") (quoting 3 Works of Alexander Hamilton 557, 559 (J. Hamilton ed. 1850)).

Thus, in establishing that preventive services must be covered if they appear in guidelines "supported by" HRSA and recommendations "from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention" that are "in effect," the Preventive Services Provision refers the development and acceptance of guidelines to agencies wholly under the Secretary's authority and subject to his supervision. 42 U.SC. § 300gg-13(a)(2)-(4); *see infra*

[21] Note 1 of the Public Health Service Act recognizes that while not *established* in Section 202 of the Public Health Service Act, CDC and HRSA are "agencies of the Service." *See* Public Health Service Act, As Amended Through Pub. L. No. 116–136, enacted March 27, 2020, https://perma.cc/QTV2-FZMP. CDC has long been part of the Public Health Service. *See*, *e.g.*, Public Health Service Reorganization Order § 1, 38 Fed. Reg. 18261 (July 9, 1973); MMWR Weekly, CDC: the Nation's Prevention Agency, (Nov. 6, 1992), https://perma.cc/4BAQ-5NSJ (reviewing CDC's history and name changes). HRSA became a component of the Public Health Service through departmental reorganizations. *See, e.g.,* 47 Fed. Reg. 38409 (Aug. 31, 1982) (establishing HRSA as an agency of the Public Health Service subject to the direction and control of the Secretary).

Part II.B.1. The Secretary thus has the power to ratify the decisions of his subordinates in these areas.

Under Plaintiffs' theory, the mere fact that the statute mentions a federal agency by name is enough to provide that agency unreviewable discretion, even when there is no question that the agency is part of and subordinate to a larger organization and its highest official is subordinate to another official. Plaintiffs cite nothing to support this novel theory. Indeed, Plaintiffs' argument contravenes basic principles of statutory interpretation. As the Supreme Court has explained, "[u]nder our precedents, when Congress wishes to 'alter the fundamental details of a regulatory scheme,' ... we would expect it to speak with the requisite clarity to place that intent beyond dispute." *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1849 (2020) (internal punctuation omitted) (quoting *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1617 (2018)). So too, here: Plaintiffs' reading would require the Court to accept that Congress rewrote the structure and authority of the Department of Health and Human Services without saying that it was doing so, and gave unreviewable authority to subordinate agency officials and an advisory committee, without saying that it was doing so. This assertion cannot be squared with the text of the provision.

Plaintiffs rely on *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania,* 140 S. Ct. 2367 (2020), to advance their contention that HRSA's discretion in accepting which guidelines it will support means such guidelines are unreviewable by the Secretary. But *Little Sisters* underscores the Secretary's authority. In that case, the Supreme Court upheld rules regarding the contraceptive coverage requirement under the Preventive Services Provision that were promulgated by the Departments of HHS, Labor, and the Treasury and *signed by the Secretary and not the HRSA Administrator* regarding the contraceptive coverage requirement. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536, 57,586 (Nov. 15, 2018) (regulations signed by HHS Secretary Alex M. Azar II). In so doing, the Court expressly upheld *the Department's* authority under the Secretary to issue those rules, not HRSA's authority to act alone. *See Little Sisters*, 140 S. Ct. at 2386 ("we hold today that *the Departments* had the statutory authority to craft that

exemption, as well as the contemporaneously issued moral exemption.") (emphasis added); *see also* 80 Fed. Reg. at 41,322 (A recommendation in HRSA supported guidelines is "considered to be issued [for purposes of the Preventive Services Provision] on the date on which it is accepted by the Administrator of HRSA, *or if applicable, adopted by the Secretary of HHS*.") (emphasis added). Plaintiffs' argument that ratification is impossible cannot be squared with the *Little Sisters* opinion's holding that the Secretary and Departments have the authority to create exemptions from guidelines that HRSA adopted.

Had Congress wanted to vest unreviewable discretion in the HRSA Administrator notwithstanding the Administrator's established position as a subordinate who reports to the Secretary—which would have been a marked departure from decades of practice in federal agencies—it would have said so explicitly. The same is true with respect to ACIP, which has long existed to provide guidance to assist the CDC Director and Secretary in those officials' efforts to carry out their duties, not to effect policy on its own. *See infra* Part II.B.1.

Even though no statutory text countermands the basic reporting structure of HHS or exempts the HRSA Administrator's and the CDC Director's recommendations and guidelines from Secretarial approval, Plaintiffs ask this Court to take it upon itself to write such an "unreviewable authority" requirement into the text here. This request, too, violates the basic rules of statutory interpretation: "It is a fundamental principle of statutory interpretation that 'absent provision[s] cannot be supplied by the courts."' This principle applies not only to adding terms not found in the statute, but also to imposing limits on an agency's discretion that are not supported by the text." *Little Sisters,* 140 S. Ct. at 2381 (quoting *Rotkiske v. Klemm*, 140 S. Ct. 355, 360-61 (2019) (in turn quoting A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 94 (2012))); *see also Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020) ("[T]his Court may not narrow a provision's reach by inserting words Congress chose to omit."). In short, Plaintiffs' proposed construction is contrary to the fundamental principle that a court should not insert its own absent text into a statute or change the basic structure of a regulatory system without Congress's express say so.

Were that not enough, Plaintiffs' proposed construction violates a third principle of statutory interpretation. Plaintiffs essentially ask the Court to interpret the Preventive Services Provision in order to create a constitutional problem when it does not need to do so. This, too, is impermissible. The Supreme Court has long held that "when deciding which of two plausible statutory constructions to adopt, a court must consider the necessary consequences of its choice. If one of them would raise a multitude of constitutional problems, the other should prevail." *Clark v. Martinez*, 543 U.S. 371, 380–81 (2005). Plaintiffs ask this Court to do the opposite, imploring it to find restrictions not in the statute's text and contrary to HHS's established regulatory structure to create a constitutional problem. There is no support for this extraordinary request.

3. Even If There Were an Appointments Clause Violation With Respect to the Coverage Requirements, the Remedy Would Be to Permit the Secretary to Exercise Authority over His Department to Ratify the Work of His Subordinates—Which He Has Already Done.

Even if Plaintiffs' reading of the statute were permissible or could be squared with the structure of HHS and the long-standing authority of the Secretary, Plaintiffs' proposed solution—that ratification by a politically accountable and constitutionally appointed principal officer is impossible and that the coverage requirements must be invalidated—cannot be squared with Appointments Clause jurisprudence.

The Supreme Court made this clear just last term in *Arthrex, Inc.*, 141 S. Ct. 1970. There, the Court held that because Administrative Patent Judges on the Patent Trial and Appeal Board ("PTAB") had "unreviewable authority . . . during inter partes review," their appointment to inferior office was unconstitutional. *Id.* at 1985. In resolving the case, however, the Court declined "to hold the entire regime of inter partes review unconstitutional." *Id.* at 1986. Instead, the Court explained,

> "[W]hen confronting a constitutional flaw in a statute, we try to limit the solution to the problem" by disregarding the "problematic portions while leaving the remainder intact." This approach derives from the Judiciary's "negative power to disregard an unconstitutional enactment" in resolving a legal dispute. In a case that presents a conflict between the Constitution and a statute, we give "full effect" to the Constitution and to whatever portions of the statute are "not repugnant" to the Constitution, effectively severing the unconstitutional portion of the statute.

Id. (citations omitted).

Accordingly, the Court held that in keeping with the PTO Director's statutory authority, which vests the Director with "'the powers and duties' of the PTO," it would remedy the constitutional defect by invalidating the statute that prohibited the Director from reviewing the PTAB's decisions. That remedy would permit the *inter partes* review scheme to continue as before but would place the ultimate review in a constitutionally-appointed principal officer of the United States. *Id.*; *see id.* at 1987-88. The Court then remanded the case to the Acting Director of the PTO for review of the PTAB's decision. In other words, the Court held that the remedy for a statutory scheme giving unreviewable authority of sufficient importance to an officer that was not appointed by the President and confirmed by the Senate is to uphold the scheme as a whole and simply provide review by a principal officer.

Plaintiffs' argument here (though incorrect for the reasons set forth elsewhere herein), is that the coverage-requirements regime established in the Preventive Services Provision is analogous to the *inter partes* regime at issue in *Arthrex*, vesting unreviewable discretion in improperly appointed officers. *See, e.g.*, Mot at 12. If that *Arthrex* argument is correct, then *Arthrex*'s remedy applies—the Secretary as a Senate-confirmed officer must have authority to review and approve the recommendations and guidelines at issue for the coverage requirements to continue in effect. Here, the Secretary has already done so, so there is no longer any further action for this Court to take. *See, e.g.*, *Guedes*, 920 F.3d at 13.

Plaintiffs attempt to avoid this straightforward result by arguing that the Preventive Services Provision would violate the Appointments Clause notwithstanding the Secretary's ratification because it would allow insurance coverage requirements to take effect *prior to* any ratification by the Secretary. Pl.'s Mot. at 24. But they cite no authority supporting this proposition, which is inconsistent with *Arthrex's* remedial holding.

This argument is not only contrary to the holding in *Arthrex*; it also cannot be squared with the well-established principle that ratification is an appropriate remedy for Appointments Clause

violations.[22] Ratification, by definition, cures instances in which a subordinate may have acted outside his or her authority. *See generally* Restatement (Second) Agency § 82 ("Ratification is the affirmance by a person of a prior act which did not bind him but which was done or professedly done on his account, whereby the act, as to some or all persons, is given effect as if originally authorized by him."). Thus, judicial decisions recognizing the availability of ratification as a remedy presume that an agent without proper authority has taken an action that can be cured by a subsequent act of a principal. Likewise, ratification necessarily applies *nunc pro tunc*—curing any lack of authority in the act *at the time the act was taken by the unauthorized agent. See, e.g.*, *Jooce v. FDA*, 981 F.3d 26, 29 (D.C. Cir. 2020) ("Here, the rulemaking record closed in 2016 and consequently Commissioner Gottlieb had no such obligation to consider new evidence in 2019" when he ratified the rule); *see also Advanced Disposal Servs. East, Inc. v. NLRB*, 820 F.3d 592, 604 (3d Cir. 2016) (concluding that NLRB properly ratified certain actions "*nunc pro tunc"*); *see generally* 1 Floyd Mecham, The Law of Agency, § 483, p. 354 (2d ed. 1914) (ratification "extends to the whole of the act—it goes back to its inception and continues to its legitimate end"). To accept Plaintiffs' argument, then, is simply to reject—contrary to law—that ratification is an appropriate remedy.[23] *See, e.g., Guedes*, 920 F.3d at 13; *Jooce*, 981 F.3d at 29.

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[22] Plaintiffs cite the holding of *Lucia v. SEC*, 138 S. Ct. 2044 (2018), that SEC's ALJs are officers of the United States who must be appointed by "the President, a court of law, or a head of department" even though their decisions are subject to review by the Securities and Exchange Commission itself. *Lucia*, 138 S. Ct. at 2051; *see* Pl.'s Mot. at 24. The court concluded that "the 'appropriate' remedy for an adjudication tainted with an appointments violation is a new 'hearing before a properly appointed' official." *Lucia*, 138 S. Ct. at 2055. But that instruction from the Court regarding how a particular adjudication should be remedied does not cast doubt on the longstanding principle that agency decisions may be ratified by a properly appointed official who has authority to take the action. *See Consumer Fin. Prot. Bureau v. Gordon*, 819 F.3d 1179 (9th Cir. 2016) (concluding that an improperly appointed official permissibly ratified his own prior acts upon receiving an appointment consistent with the Appointments Clause.) And here, the HRSA Administrator and CDC Director who currently approve the recommendations and guidelines in order for the coverage requirements to take effect are officers of the United States who are constitutionally appointed by the Secretary, a head of department, unlike the ALJ at issue in *Lucia*, *see id*. at 2051. *See infra* Part II.B.1.

[23] Additionally, even if Plaintiffs were correct that coverage requirements under 42 U.S.C. § 300gg-13(a) could not take effect until after ratification by a principal officer, the January 21

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In sum, because the Secretary has ratified all currently in-effect recommendations that give rise to coverage requirements under the Preventive Services Provision, any putative Appointments Clause violation has already been "resolved on the merits" and any appropriate remedy has already been effected.

B. The Preventive Services Provision's Coverage Requirements Are Constitutional Even Absent Explicit Secretarial Ratification

Although the Secretary's ratification is sufficient to resolve Plaintiffs' Appointments Clause claim, it is not necessary to rely on that ratification to sustain the preventive-service provisions. None of those provisions violates the Appointments Clause. The HRSA Administrator and CDC Director—the officials upon whose decisions the coverage requirements under Sections (a)(2)-(a)(4) of the Preventive Services Provision take effect—are both inferior officers of the United States who are appointed by the Secretary consistent with the Appointments Clause and subject to the Secretary's supervision, so the coverage requirements based on the guidelines and recommendations they have adopted are constitutionally promulgated. The PSTF, by contrast, is an independent body that does not exercise Executive Power. Its independent recommendations

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ratification means Plaintiffs lack a basis to pursue that claim in this lawsuit as all of the coverage provisions at issue in this litigation have now been ratified. Even assuming Plaintiffs would have benefitted from a prospective invalidation of an unratified coverage requirement pending ratification—*but see* Part I, *supra*—their complaint about the allegedly improper gap between effectiveness and ratification is now a purely retrospective complaint. And Plaintiffs have not identified a waiver of sovereign immunity that would entitle them to seek a retrospective remedy for that alleged problem. *See, e.g.*, *Lane v. Pena*, 518 U.S. 187, 192 (1996) ("A waiver of the Federal Government's sovereign immunity must be unequivocally expressed in statutory text."). Even if they had proved that the coverage requirements raised their premiums in the past, they cannot pursue a claim for money damages against the United States here. *See, e.g.*, *Rothe Dev. Corp. v. U.S. Dep't of Def.*, 194 F.3d 622, 624 (5th Cir. 1999) (Administrative Procedure Act is "[a] waiver as to injunctive relief—but not monetary damages"). Because they cannot gain any relief with respect to their purported injuries, they cannot pursue their claims. *See Dierlam v. Trump*, 977 F.3d 471, 476 (5th Cir. 2020) ("If an intervening event renders the court unable to grant the litigant 'any effectual relief whatever,' the case is moot." (quoting *Calderon v. Moore*, 518 U.S. 149, 150 (1996)). Now that all coverage requirements have been ratified, this Court should decline to consider the purely academic question whether effectiveness of a given coverage requirement should have awaited ratification.

about the quality of evidence backing the effectiveness of certain preventive services is separate from any judgment about what should or should not be covered by health insurance, which latter judgment was made by Congress. But even if the Court should disagree and conclude that the PSTF is exercising Executive Power, the remedy under both the Appointments Clause and the Vesting Clause is the same—permitting the Secretary to ratify its recommendations for purposes of allowing the preventive-care coverage requirements to remain in effect. As the Secretary has already ratified the recommendations, Defendants are entitled to judgment in their favor on Plaintiffs' Appointments Clause and Vesting Clause claims in any event.

1. As Inferior Officers, the HRSA Administrator and CDC Director's Issuance of the Coverage Requirements Is Consistent with the Appointments Clause

The preventive services covered by Section 300gg-13(a)(2) take effect only if the CDC Director adopts a recommendation by ACIP, and the services covered by Sections 300gg-13(a)(3) & (4) take effect only if the guidelines addressing those services are supported by the HRSA Administrator. As both the CDC Director and HRSA Administrator are non-career SES officers appointed by the Secretary, there is no defect in either their appointment or authority to accept the recommendations and guidelines for purposes of the preventive services provision.

Under the Appointments Clause, inferior officers may be appointed by "the President, 'Courts of Law,' or 'Heads of Departments'" without Senate confirmation if Congress vests those officers' appointing authority in one of those three entities. *Lucia*, 138 S. Ct. at 2050; U.S. Const. Art. II, § 2, cl. 2. But "Article II does not require that a law specifically provide for the appointment of a particular inferior officer." *Willy v. Admin. Rev. Bd.*, 423 F. 3d 483 (5th Cir. 2005) (citation omitted). Instead, the Fifth Circuit has held that "[t]he broad language employed by Congress" in an agency's Reorganization Plan "and in 5 U.S.C. § 301 vests the Secretary with ample authority to . . . appoint [inferior officers] and delegate final decision-making authority to them." *Id.* at 491-92; *see id.* at 494.

Willy upheld the appointment of inferior adjudicative officers in the Department of Labor by the Secretary of Labor pursuant to Reorganization Plan No. 6 of 1950 explaining that under than plan, Congress had "imbue[d]" the Secretary of Labor with authority to appoint those officers. 423 F.3d at 492. Here, the Secretary of HHS has identical authority to appoint inferior officers in the Public Health Service under Reorganization Plan No. 3 of 1966.[24] *Willy* applies to the materially indistinguishable circumstances here. Both the CDC Director and the HRSA Administrator are non-career SES officers in the Public Health Service appointed by the Secretary of HHS, the head of their department. APP 038, LeFevre Decl. ¶¶ 6-8. Accordingly, under *Willy*, they were constitutionally appointed.

With the constitutional appointment of the CDC Director and the HRSA Administrator, Plaintiffs' Appointments Clause claims must fail as to 42 U.S.C. §§ 300gg-13(a)(2)-(4). Although Plaintiffs refer to "members" of HRSA in their brief, there is no such thing—HRSA is a federal agency headed by an Administrator, and "a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued" for purposes of the Preventive Services Provision "on the date on which it is accepted by the Administrator of HRSA." 80 Fed. Reg. at 41,322. Thus, for purposes of the coverage requirements of the Preventive Services Provision for the HRSA-supported guidelines, it is only the Administrator's appointment that is relevant.

Similarly, it is the CDC Director's appointment that is relevant with respect to ACIP. As a federal advisory committee, ACIP exists to "provide advice and guidance to the [CDC Director] regarding the use of vaccines and related agents." APP 148, ACIP Charter at 1 (Description of Duties). In exercising the duties in which she is advised by ACIP, the CDC Director, in turn, is exercising delegated authority from the Secretary of HHS pursuant to Sections 311 and 317 of the Public Health Service Act.[25] And in order for a recommendation from ACIP to be "in effect" as

[24] *Compare* Reorganization Plan No. 6 of 1950 §§ 1-2, 5 U.S.C. app. 1 *with* Reorganization Plan No. 3 of 1966 §§ 1-2, 5 U.S.C. app. 1.

[25] *See* APP 148, ACIP Charter at 1 (Objective and Scope of Duties) ("The Secretary, Department of Health and Human Services . . . , and by delegation the Director, Centers for Disease Control and Prevention . . . , are authorized under Section 311 and Section 317 of the Public Health Service

required to be covered under the Preventive Services Provision, it must be "reviewed by the CDC Director," "adopted" by the CDC Director, and "published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report." APP 148, ACIP Charter at 1 (Description of Duties); *see also* 45 C.F.R. § 147.130(a)(1)(ii) ("a recommendation or guideline of [ACIP] is considered issued on the date on which it is adopted by the Director of the CDC").[26]

Moreover, the roles of the CDC Director and HRSA Administrator with respect to the Preventive Services Provision are indisputably those of inferior officers. As Plaintiffs conceded, "[w]hether one is an 'inferior' officer depends on whether he has a superior other than the President. An inferior officer must be directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Arthrex*, 141 S. Ct. at 1980 (citations omitted and cleaned up). The Court noted that the PTAB judges at issue in *Arthrex* were appointed as inferior officers but could not be directed and supervised as inferior officers because their decisions were "insulat[ed] from review" and "their offices [were insulated] from removal. *Id.* at 1986. But no similar insulation exists here: the CDC Director and HRSA Administrator have no tenure protections and serve at the pleasure of the Secretary. *See* 5 U.S.C. § 7543 (applying tenure-based protections in the SES only to an "employee"); *id.* § 7541(1)

Act, [42 U.S.C. §243 and 42 U.S.C. §247b], . . . to assist states and their political subdivisions in the prevention and control of communicable diseases[and] to advise the states on matters relating to the preservation and improvement of the public's health . . .."); *see also* 42 U.S.C. § 243(a); *id.* § 247b(a).

[26] Plaintiffs demand an "example where the CDC Director has overruled an ACIP recommendation." Mot at 23. Although an example is not necessary for the Director to have the power to decline to adopt ACIP's recommendations as expressly set forth in ACIP's Charter, one such example was widely publicized in the weeks just before Plaintiffs filed their motion, when the CDC Director recommended booster shots for the Pfizer-BioNTech COVID-19 vaccine for adults at high risk of disease from occupational and institutional exposures to COVID-19, although ACIP's recommendation for booster shots at the time did not include these workers. *See, e.g.*, Apoorva Mandavilli & Benjamin Mueller, CDC Chief Overrules Agency Panel and Recommends Pfizer-BioNTech Boosters for Workers at Risk, N.Y. Times (Oct. 21, 2021), https://perma.cc/37X7-EDF4; CDC, Statement on ACIP Booster Recommendations (Sept. 24, 2021), https://perma.cc/Y69L-PHZM.

(defining "employee" for purposes of SES tenure protections to include only "a *career* appointee in the Senior Executive Service") (emphasis added); *cf. id.* § 3132(a)(2)(7) (SES includes "noncareer appointee[s]"); *see also* 5 C.F.R. § 317.605(b) ("An agency may terminate a noncareer or limited appointment at any time" upon "a written notice at least 1 day prior to the effective date of the removal.").

Further, because (1) both the HRSA Administrator and CDC Director exercise the authority vested in the Secretary and delegated to them by the Secretary and (2) the Preventive Services Provision does not by its terms limit the Secretary's ability to review their actions, *see supra* Part II.A.2, their actions remain under the Secretary's control. In short, because ACIP only exists in order to *advise* the CDC Director in executing functions *delegated by* the Secretary and its recommendations only take "effect" under the statute when adopted by the CDC Director, the Secretary has ultimate authority over its recommendations. Likewise, HRSA was created by the Secretary to exercise functions vested in the Secretary, so the Secretary has ultimate authority over the HRSA-supported guidelines. For these reasons, Plaintiffs' Appointments Clause claim must fail as to the HRSA-supported guidelines and CDC adopted ACIP recommendations, even in the absence of the Secretary's ratification.

2. The PSTF is an Independent Body Whose Standards Congress Appropriately Incorporated into the ACA

As it applies to PSTF, Plaintiffs' claim is based on a different fundamental misapprehension of the PSTF's role under the Preventive Services Provision. Plaintiffs mistakenly contend that in making its recommendations of preventive services, some of which are incorporated into insurance coverage requirements by operation of the Preventive Services Provision, PSTF members act as "officers of the United States" requiring presidential appointment pursuant to the Appointments Clause.

The PSTF is a volunteer body of "nationally-recognized non-Federal experts in prevention and evidence-based medicine." APP 066, USPSTF Procedure Manual § 1.3. Its purpose is "to improve the health of all Americans by making evidence-based recommendations about clinical

preventive services and health promotion. *Id.* § 1.1; *see also* 42 U.S.C. § 299b-4(a)(1). Its recommendations are typically published in peer reviewed journals, not government publications like the Federal Register. *See id.* §1.10. While the PSTF is supported by AHRQ, a federal agency within HHS, it is not part of that agency. Rather, AHRQ's role is to "provide ongoing administrative, research, and technical support for the operations of the Task Force[.]" 42 U.S.C. § 299b-4(a)(3).

By law, "[a]ll members of the Task Force . . . and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure." *Id.* § 299b-4(a)(6). It is thus not a government agency and is not expressing the position of the United States government; as its published recommendation statements make clear, "[r]ecommendations made by the USPSTF are independent of the US government. They should not be construed as an official position of AHRQ or the US Department of Health and Human Services." APP 162, PrEP Recommendation at 2211.

The Preventive Services Provision does not establish the PSTF as an executive body or provide PSTF with law enforcement or policymaking discretion. *Cf. Lucia*, 138 S. Ct. 2052 ("exercis[ing] significant discretion" in the course of "tak[ing] testimony, conduct[ing] trials, rul[ing] on the admissibility of evidence, and . . . enforc[ing] compliance with discovery orders" makes SEC ALJ's officers of the United States for purposes of the Appointments Clause); *Buckley v. Valeo*, 424 U.S. 1, 138 (1976) ("discretionary power to seek judicial relief" is "ultimate remedy for a breach of the law" delegated by the Constitution to the executive to be held by officers appointed pursuant to the Appointments Clause). Nor does the Preventive Services Provision authorize PSTF to make decisions about insurance coverage. The Preventive Services Provision simply incorporates evolving standards of this body with medical expertise chosen by Congress to effectuate *Congress's* judgment that standard contemporary preventive services be covered by health insurance.

In other words, the expert body referenced in the statute simply makes decisions about what standard preventive medical care should look like, while Congress itself made the decision

that whatever this standard care is should generally be covered by insurance. This approach is consistent with numerous statutes that incorporate by reference independent recommendations without creating any requirement that the heads of the recommending bodies be appointed as officers of the United States. *See, e.g.*, 4 U.S.C. § 119(a)(2) (electronic databases established by states "shall be provided in a format approved by the American National Standards Institute's Accredited Standards Committee X12"); 16 U.S.C. § 3372(a)(2)(A) (rendering it unlawful to import "any fish or wildlife taken, possessed, transported, or sold in violation of any law or regulation of any State or in violation of any foreign law"); 18 U.S.C. § 13(a) (establishing that those who commit acts on federal land "not made punishable by any enactment of Congress, [that] would be punishable [under State law if the state had jurisdiction] . . . by the laws thereof in force at the time of such act or omission, shall be guilty of a like offense and subject to a like punishment" as under State law); 42 U.S.C. § 6293(b)(8) ("Test procedures for water closets . . . shall be the test procedures specified in ASME A112.19.6–1990 . . . . If the test procedure requirements of ASME A112.19.6–1990 are revised at any time and approved by ANSI, the Secretary shall amend the test procedures . . . . to conform to such revised ASME/ANSI requirements[.]"). Of course, no one understands the heads of independent bodies like ANSI, or heads of state governments or foreign states, to be "officers of the United States" simply because their rules or standards are incorporated into federal statutes.[27] So too, here. Congress made the choice to incorporate the contemporary standards for preventive care as services it wanted to be covered by insurance, with those standards determined by an independent body of medical experts according to evidence-based expertise. Exercise of this scientific expertise is not an exercise of policy discretion or the Executive Power, and it does not require appointment pursuant to the Appointments Clause.

[27] Plaintiffs attempt to distinguish ANSI and other independent bodies on the ground that the PSTF was established by statute and is supported by the federal government, but the OLC opinion on which they rely makes clear that being created by law is not a necessary condition of an "office" under the Appointments Clause. *See* 31 U.S. Op. Off. Legal Counsel 73, 2007 WL 1405459, at *10 (Apr. 16, 2007). The important distinction—which the PSTF shares—is that the independent organizations are taking their own actions independently for their own purposes, and not doing so to enforce, interpret, or administer federal law. *See id.* at *9, *11.

PSTF members are certainly not "officers" subject to the Appointments Clause under the binding law of this Circuit. The Fifth Circuit, sitting *en banc*, has held that "Supreme Court precedent has established that the constitutional definition of an 'officer' encompasses, at a minimum, a continuing and formalized relationship of employment with the United States Government," such that officials who do not have such a relationship need not be appointed pursuant to the Appointments Clause. *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001) (en banc); *see also United States v. Hartwell*, 73 U.S. 385, 393 (1867) ("An office is a public station, or employment, conferred by the appointment of government. The term embraces the ideas of tenure, duration, emolument, and duties."); *see also United States v. Germaine*, 99 U.S. 508, 511 (1878) (Civil surgeon appointed by pensions commissioner was not an "officer" under the Appointments Clause because, *inter alia,* "no regular appropriation is made to pay his compensation.").

Members of the PSTF do not meet the "minimum" criteria set forth in *Riley*. The PSTF "is made up of 16 volunteer members who are nationally recognized experts in prevention, evidence-based medicine, and primary care."[28] *See* 85 Fed. Reg. 711, 712 (Jan. 7, 2020) (PSTF "members are all volunteers and do not receive any compensation beyond support for travel to in person meetings."). Any role staffed by part-time volunteers is, by definition, not a "continuing and formalized relationship of employment with the United States Government," requiring appointment pursuant to the Appointments Clause.[29] *Riley*, 252 F.3d at 757.

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[28] U.S. Preventive Servs. Task Force, Our Members, https://perma.cc/XS2F-V2CD.

[29] Plaintiffs attempt to distinguish *Riley* by claiming that "employment" means something other than its plain meaning. *See* Pl's Mot at 16-18; *cf. Riley*, 252 F.3d at 758 ("qui tam plaintiffs are not officers because they do not draw a government salary and are not required to establish their fitness for public employment"). The OLC opinion on which Plaintiffs rely, however, makes clear that *Riley* is consistent with prior OLC opinions taking the position that "employment within the federal government" was "essential" to an "office" for purposes of the Appointments Clause. *See* 31 U.S. Op. Off. Legal Counsel 73, 2007 WL 1405459, at *4. Whatever the merits of the analysis of either *Riley* and the prior OLC opinions consistent with it, on the one hand, or the 2007 OLC opinion on which Plaintiffs rely, on the other, *Riley*'s construction is the one that is binding on this Court.

Plaintiffs rely not on judicial precedent, but rather on a 2007 Office of Legal Counsel Opinion that concludes that an "office" subject to the Appointments Clause has two characteristics— that "(1) it is invested by legal authority with a portion of the sovereign power of the federal government; and (2) it is 'continuing.'" But that opinion does not help Plaintiffs, for even under the OLC analysis, it is clear that PSTF members are not "officers of the United States" that must be appointed in conformity with the Appointments Clause.

The 2007 OLC opinion on which Plaintiffs rely makes clear that "invest[ment] by legal authority with a portion of the sovereign power of the federal government" that creates a public office "'involves necessarily the power to (1) legislate, or (2) execute the law, or (3) hear and determine judicially submitted questions.'" 31 U.S. Op. Off. Legal Counsel 73, at *9 (quoting House of Judiciary Committee Report of 1899, published in Asher C. Hinds, 1 Hinds' Precedents of the House of Representatives, 604, 607 (1907)); *see id.* at *11 (explaining that "delegated sovereign authority" within the meaning of the test "primarily involves the authority to administer, execute, or interpret the law"). The PSTF does none of these things, and thus does not hold "a portion of the sovereign power of the federal government." So its members do not hold federal "offices."

Supreme Court precedent on the Appointments Clause is consistent with the requirement that federal "officers" have the power to legislate, execute, administer, or interpret the law. In *Buckley v. Valeo*, 424 U.S. 1 (1976), the Court explained the concern that "Congress has given the [Federal Election] Commission wide-ranging rulemaking and enforcement powers with respect to the substantive provisions of the Act." *Id.* at 118. The Court found that "vesting in the Commission primary responsibility for conducting civil litigation in the courts of the United States for vindicating public rights, violate[d]" the Appointments Clause, and that "the Commission's broad administrative powers: rulemaking, advisory opinions, and determinations of eligibility for funds and even for federal elective office itself" required appointments in a manner consistent with the Appointments Clause. *Id.* at 140-41. This was so, the Court concluded, because the Commission's

enforcement powers were akin to the executive power exercised by the Attorney General, while the other powers were "more legislative and judicial in nature." *Id.*

Similarly, in *Lucia v. S.E.C.,* 138 S. Ct. 2044 (2018), the Court held that the Securities and Exchange Commission's ALJs were officers because they exercised "nearly all the tools of federal trial judges" and at the close of a hearing issued opinions that can be "deemed the action of the Commission" without further review. *Id.* at 2054-54. And in *Arthrex*, the Court found that Administrative Patent Judges who issued final written decisions in patent appeals after a process "which resembles civil litigation in many respects" were officers. 141 S. Ct. at 1977. All of these cases where the Court concluded that a federal office existed involved the exercise of power akin to administering, executing, drafting, or interpreting law.[30]

The offices at issue in these cases are wholly distinct from the functions performed by the volunteer scientific body that is the PSTF. Far from writing, interpreting, administering, or executing law, PSTF's "mission is to improve the health of [all Americans] by making evidence-based recommendations about clinical preventive services and health promotion." APP 066, USPSTF Procedure Manual § 1.1; *see* APP 066-067, § 1.4 (PSTF "comprehensively assesses evidence and makes recommendations about the effectiveness of clinical and primary and secondary preventive services"). Unlike an agency tasked with writing regulations in order to

[30] This is consistent with every other Appointments Clause case addressing a position that the court understood to be an "office" for purposes of the Appointments Clause cited in either party's opening brief in which the Appointments Clause issue does not turn on the relationship of government employment. *See Edmond v. United States*, 520 U.S. 651, 662 (1997) (Coast Guard Court of Criminal Appeals judges "ensure that the court-martial's finding of guilt and its sentence are correct in law and fact, which includes constitutional challenges") (citation omitted); *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868, 881-82, 891 (1991) (Tax Court special trial judges are inferior officers who "take testimony, conduct trials, and . . . enforce compliance with discovery orders"); *Willy,* 423 F.3d at 491 (Department of Labor Administrative Review Board members who issue "final agency decisions on questions of law and fact" assumed to be inferior officers) (citation omitted); *cf. Hartwell*, 73 U.S. 385 (1867) (clerk of Assistant Treasurer an officer because his "employment . . . was in the public service of the United States" and "his compensation was fixed by law"); *Germaine*, 99 U.S. at 512; *Riley*, 252 F.3d at 757-58 (qui tam relators do not hold an "office" because they "do not draw a government salary").

elaborate or clarify how a statute is to be administered or enforced—to exercise authority to decide specific gaps in a statute left by Congress in accordance with the statute's meaning and purpose—PSTF's role is *not* to make cost/value judgments about what services merit insurance coverage or not, nor is it to interpret what Congress intended to cover when setting broad criteria for insurance coverage. *Congress* already made the decision about what to include in insurance plans, and so the coverage choice—the only aspect of PSTF's role that Plaintiffs contend qualifies as "significant authority" under the Appointments Clause—is not exercised by the PSTF. PSTF members instead are to evaluate the evidence regarding medical preventive services and determine the degree to which the science supports their being provided to certain populations. In other words, the duties the PSTF is charged with carrying out are wholly independent of the function for which Congress has chosen to use its work in the Preventive Services Provision. Accordingly, PSTF volunteers who meet just a few times a year do not transform into "officers" under the Appointments Clause just because their work has an effect that is incidental to their purposes and is used by Congress in a separate statutory provision for a purpose the PSTF is not charged with considering and that is not used as a basis for its recommendations.

Plaintiffs' Vesting Clause claim, which is addressed only to the recommendations of the PSTF, also fails for the same reasons. The PSTF's recommendations, as incorporated into the ACA, are not exercises of the Executive or Legislative Power. They are "evidence-based" scientific recommendations about the contemporary standard of care in preventive medicine. 42 U.S.C. § 300gg-13(a)(1). As discussed above, Congress made the judgment to incorporate evolving contemporary standards into the ACA so that whatever preventive care services were part of the "current" standard would be covered. *Id.* Just as independent bodies like ANSI, foreign governments, or state legislatures are not exercising the Legislative Power or the Executive Power, neither is the PSTF.[31]

[31] The only case Plaintiffs cite in support of their Vesting Clause claim, *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct 2183 (2020), does not support Plaintiffs' position here. In that case, the Supreme Court found that the multiple layers of tenure protection

3. If, In the Alternative, the Court Finds that PSTF Exercises Executive Power, the Secretary's Ratification Cures Any Constitutional Violation

However, should the Court conclude that the PSTF exercises Executive power and is thus subject to the Appointments Clause, the proper remedy is not invalidation of the coverage requirements under 42 U.S.C. § 300gg-13(a)(1). Rather, if the Court concludes that the PSTF is subject to the Appointments Clause, it is appropriate to read the statute to authorize review of its recommendations by the Secretary of HHS for purposes of the Preventive Services Provision's coverage requirement. Because the Secretary has already ratified the current recommendations of the PSTF, there is no further remedy to which Plaintiffs are entitled under either their Appointments Clause claim with respect to Section (a)(1) of the Preventive Services Provision or under their Vesting Clause claim.

As noted above, the statute establishing the PSTF provides that "[a]ll members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure." 42 U.S.C. § 299b-4(a)(6). But if the Court concludes that the PSTF is in fact subject to the Appointments Clause, it should hold that, for purposes of the Preventive Services Provision's coverage requirements, it is not "practicable" to insulate the PSTF's recommendations from review by the Secretary.[32] This

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provided to the CFPB Director violated Article II's Vesting Clause. *See id.* at 2192. PSTF members have no tenure protections (and for the reasons explained above, do not even exercise Executive Power), so *Seila Law* has no relevance to the merits of Plaintiffs' claim. To the extent *Seila Law* is relevant to the Vesting Clause claim here, it supports Defendants' argument that—if the Court disagrees with Defendants on the merits of the claim—the appropriate remedy is to sever PSTF's statutory independence in the context of the Preventive Services Provision and leave the remainder of the scheme intact. *See infra* Part II.B.3.

[32] It would also be appropriate to permit review by the AHRQ Director, head of the agency that supports the PSTF. *See* 42 U.S.C. § 299b-4(a). The AHRQ Director is an inferior officer appointed by the Secretary pursuant to statute. *See* 42 U.S.C. § 299(a).

construction would be appropriate to avoid constitutional problems created by a reading that did not permit review by duly appointed officers of the United States. *See, e.g.*, *Clark*, 543 U.S. at 380–81. And pursuant to this construction, the Secretary's ratification cures any constitutional violation. *See supra* Part II.A.

Even if the Court were to both (a) hold that the Preventive Services Provision's coverage requirement with respect to PSTF's recommendations mandates that a duly appointed officer appropriately vested with Executive Power issue recommendations covered by the statute and (b) reject the reading of Section 299b-4(a)(6) presented above that would avoid the constitutional issue, the Secretary's ratification would *still* cure any violation and necessitate judgment for Defendants on Plaintiffs' Appointments Clause and Vesting Clause claims. This is because, as discussed *supra* Part II.A.3, *Arthrex* requires a narrow remedy to give as much effect to the constitutional provisions of a statutory scheme as possible. In the context of the PSTF, *Arthrex*'s remedial holding mandates holding Section 299b-4(a)(6) unenforceable to the extent it precludes the Secretary's review and approval of PSTF's recommendations for purposes of the Preventive Services Provision's coverage requirements. *See also Seila Law*, 140 S. Ct. at 2209 ("[W]hen confronting a constitutional flaw in a statute, we try to limit the solution to the problem, severing any problematic portions while leaving the remainder intact."); *id.* at 2210-11 ("We think it clear that Congress would prefer that we use a scalpel rather than a bulldozer in curing the constitutional defect we identify today."). Accordingly, because the Secretary has already ratified the current recommendations of the PSTF that are subject to the Preventive Services Provision's coverage requirements, the same result must hold: Any constitutional violation has been cured, and judgment should be entered for Defendants with respect to Plaintiffs' Appointments Clause claim as it relates to the PSTF and with respect to Plaintiffs' Vesting Clause claim.

III. THE PREVENTIVE SERVICES PROVISION DOES NOT VIOLATE NONDELEGATION PRECEDENTS

The delegations at issue under 42 U.S.C. § 300gg-13(a) are narrower than delegations that have been upheld by the Fifth Circuit and the Supreme Court. Since the filing of this lawsuit, the Fifth Circuit has rejected another nondelegation challenge to a federal statute. In *Big Time Vapes, Inc. v. Food & Drug Administration*, 963 F.3d 436 (5th Cir. 2020), the Fifth Circuit upheld the provision of the Family Smoking and Tobacco Control Act that made certain tobacco products (like cigarettes) subject to the Act's requirements and provided that the Act's requirements also would apply "to any other tobacco products that" the agency "by regulation deems to be subject to [the Act]." *Id.* at 438 (brackets in original) (footnote omitted) (quoting 21 U.S.C. § 387a(b)).

Rejecting that nondelegation challenge, the Fifth Circuit set out principles established by more than 80 years of Supreme Court precedent. The court explained that "[d]elegations are constitutional so long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized [to exercise the authority] is directed to conform.'" *Big Time Vapes*, 963 F.3d at 441 (citation omitted). "It is 'constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority.'" *Id.* (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)).

The court emphasized that "[t]hose standards . . . are not demanding." *Id.* at 442 (quotation marks omitted). Even though Congress has delegated authority since "the beginning of the government," *id.* (quotation marks omitted), the Supreme Court "has found only two delegations to be unconstitutional," *id.* at 446. One "provided literally no guidance for the exercise of discretion," and the other "conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001) (referring to *Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)).

By contrast, in the more than 80 years since those decisions, the Supreme Court has consistently upheld "Congress' ability to delegate power under broad standards," *Mistretta v. United States*, 488 U.S. 361, 373 (1989), and "ha[s] 'almost never felt qualified to second-guess

Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law,'" *American Trucking*, 531 U.S. at 474-475 (quoting *Mistretta*, 488 U.S. at 416 (Scalia, J., dissenting)). The Supreme Court has upheld statutes authorizing the Secretary of War to determine and recover "excessive profits" from military contractors, *Lichter v. United States*, 334 U.S. 742, 785-86 (1948) (quotation marks omitted); authorizing the Price Administrator to fix "fair and equitable" commodities prices, *Yakus v. United States*, 321 U.S. 414, 420 (1944) (quotation marks omitted)); authorizing the Federal Communications Commission to regulate broadcast licensing as "public interest, convenience, or necessity" requires, *National Broad. Co. v. United States*, 319 U.S. 190, 225–26 (1943) (quotation marks omitted); authorizing the Securities and Exchange Commission to ensure that a holding company's structure does not "unfairly or inequitably distribute voting power among security holders," *American Power & Light*, 329 U.S. at 104-05; directing the Sentencing Commission to promulgate then-binding Sentencing Guidelines for federal crimes, *Mistretta*, 488 U.S. at 374-77; and directing the Environmental Protection Agency to set nationwide air-quality standards limiting pollution to the level required to "protect the public health," *American Trucking*, 531 U.S. at 472 (quotation marks omitted).

The Fifth Circuit has likewise "uniformly upheld Congress's delegations." *Big Time Vapes*, 963 F.3d at 442 n.17 (citing, as examples, *United States v. Jones*, 132 F.3d 232, 239-40 (5th Cir. 1998) (upholding delegation of authority to the Department of Justice to "define nonstatutory aggravating factors" to determine which offenders were "death-eligible" under the Federal Death Penalty Act); and *United States v. Mirza*, 454 F. App'x 249, 256 (5th Cir. 2011) (per curiam) (upholding International Emergency Economic Powers Act's delegation, which authorizes the President to declare a national emergency and limit certain types of economic activity related to that threat)).

The grants of authority under 42 U.S.C. § 300gg-13(a) fall well within the wide range of delegations approved by the Supreme Court and the Fifth Circuit and are consistent with established limits on Congress's power to delegate. "[T]he degree of agency discretion that is

acceptable varies according to the scope of the power congressionally conferred." *American Trucking*, 531 U.S. at 475. Here, Congress "constrict[ed]" the PSTF's, ACIP's, and HRSA's authority "to a narrow and defined category," *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009), "by making many of the key regulatory decisions itself," *Big Time Vapes*, 963 F.3d at 445. Congress made the "critical policy decision[ ]," *id.* at 443, that issuers offering group or individual health insurance provide coverage for preventive services without "cost sharing requirements," 42 U.S.C. § 300gg-13(a).

For each of the provisions at issue, Congress set forth sufficient guidance on the relevant entities' discretion to satisfy the intelligible-principle test. First, although Congress did not "delegate" power to the PSTF at all, but instead incorporates its work, even if 42 U.S.C. § 300gg-13(a)(1) is read as a delegation, it satisfies the standard. In that section, Congress mandated that the "items or services" must be "evidence-based," which by itself would be sufficient to satisfy the nondelegation precedents described above. 42 U.S.C. § 300gg-13(a)(1). And Congress further required the items and services must "have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force[.]" *Id.* Further, contrary to Plaintiffs' suggestions, the requirement to have a particular rating in effect by the PSTF is not merely leaving it to the PSTF to set the scope of its own work, because Congress has also given intelligible principles to the PSTF in how it is to approach making its recommendations. The PSTF is tasked to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations[.]" 42 U.S.C. § 299b-4(a)(1). Those statutory provisions supply sufficient guidance and limitations on the PSTF's decision making, and thus section (a)(1) of the Preventive Services Provision satisfies the requirement of nondelegation precedents to the extent it is (incorrectly) considered a "delegation" to begin with.

The requirements of § 300gg-13(a)(2) likewise offer sufficient boundaries and guidance on the exercise of agency discretion. That provision requires that the treatment at issue be

"immunizations" and that they have "a recommendation from the [ACIP] with respect to the individual involved[.]" 42 U.S.C. § 300gg-13(a)(2). Plaintiffs claim that those are boundaries on authority, not guidance on exercising authority, but Plaintiffs provide no precedent supporting that distinction, and it collapses on close examination. The agency's authority to impose coverage requirements under § 300gg-13(a)(2) requires it to determine that the recommendations exist with respect to the individual involved and be a recommendation for immunization, seriously limiting its discretion and identifying exactly what the agency must consider. If § 300gg-13(a)(2) instead empowered the agency to impose a coverage requirement for any medical service that is in the "public interest," Plaintiffs could not dispute that the delegation there would satisfy nondelegation precedents, *see National Broad. Co.*, 319 U.S. at 225–26, yet it is not clear how the agency's discretion under that extremely broad standard would have *greater* guidance for its exercise than it would under the language in the statute as it currently reads. Furthermore, in requiring that a potential immunization requirement have a recommendation from ACIP, Congress was pointing to a recommendation process that already existed prior to the passage of the ACA—indeed, as discussed earlier, ACIP already had a recommendation in effect for the HPV vaccine at the time of the ACA's passage. The updated HPV vaccine recommendations are the only ACIP recommendations Plaintiffs challenge in this case. Plaintiffs have not explained how Congress can fail to give an agency sufficient guidance by specifically identifying what the agency should do and pointing to how it's already been doing it.

The same analysis holds for § 300gg-13(a)(3). There, the statute dictates incorporation only for "infants, children, and adolescents," and only for "evidence-informed preventive care and screenings" identified in "comprehensive guidelines." 42 U.S.C. § 300gg-13(a)(3). In that provision, Congress offered ample guidance to the agency, by defining the relevant categories of medical treatment (preventive care and screenings), identifying the relevant population for that treatment (infants, children, and adolescents), and setting forth a further criterion for identifying appropriate treatment (that it be "evidence-informed"). Plaintiffs' assertion that more is required is inconsistent with the century of nondelegation principles described above.

Finally, the statutory requirement to develop guidelines for women's preventive care, § 300gg-13(a)(4), also satisfied nondelegation precedents. Congress confined HRSA's role to supporting guidelines for a narrow category of services—"with respect to women," such "additional preventive care and screenings" that are not otherwise encompassed by the current recommendations of the United States Preventive Services Task Force," *id.* § 300gg-13(a)(4).

Pursuant to that instruction, the HRSA guidelines for women's preventive services are developed through a transparent methodology by an expert panel.[33] Items are only eligible to be considered for inclusion in the guidelines if they "include conditions that affect a broad population of women; that are specific, more common, more serious, or differ in women; and for which prevention would have a large potential impact on women's health and well-being."[34] There is a rigorous evidence-review process for assessing such items.[35] Using that methodology, HRSA has since 2011 updated its women's preventive services guidelines to reflect new medical evidence and scientific developments relating to, among other items, breastfeeding services and supplies, screening for cervical cancer, screening for gestational diabetes mellitus, screening for interpersonal and domestic violence, well-woman preventive visits, and screening for diabetes mellitus after pregnancy.[36] This is a narrow and defined group of preventive services for women.

HRSA's authority to support guidelines for additional preventive care and screenings for women is more cabined than, for example, the authority to set "fair and equitable" commodities prices, *Yakus*, 321 U.S. at 420, or to regulate broadcast licensing as "public interest, convenience, or necessity" requires, *National Broad. Co.*, 319 U.S. at 225-26. "Congress painted much of the regulatory canvas," permissibly "leaving the finishing touches" to HRSA. *Big Time Vapes*, 963 F.3d at 446; *see also Gundy v. United States*, 139 S. Ct. 2116, 2136 (2019) (Gorsuch, J., dissenting)

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[33] Women's Preventative Servs. Initiative, Recommendations, https://perma.cc/5QZY-Y4YG.

[34] *Id.*

[35] *Id.*

[36] HRSA, Women's Preventive Services 2016 Guidelines, https://perma.cc/Y7J4-TQ78; HRSA, Women's Preventive Services Guidelines, https://perma.cc/6ANM-G4D7.

("[A]s long as Congress makes the policy decisions when requiring private conduct, it may authorize another branch to 'fill up the details.'") (quoting *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 43 (1825)).

Plaintiffs make no serious effort to reconcile their position here with the delegations upheld by the Supreme Court and the Fifth Circuit. Moreover, Plaintiffs incorrectly assert that, in assigning HRSA responsibility to support guidelines for additional preventive care and screenings for women that should be covered without cost sharing, the ACA "does not even require these agencies to make these decisions based on the 'public interest' or the 'public health[.]'" Mot. 24–25. In defining the scope of delegated authority, a court looks at the text in context and in light of the statute's purpose. *Big Time Vapes*, 963 F.3d at 443 (citing *Gundy*, 139 S. Ct. at 2126 (plurality)). The ACA was designed to "expand health insurance coverage," *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 567 (2012), and "broaden access to healthcare," *Morris v. California Physicians' Service*, 918 F.3d 1011, 1016 (9th Cir. 2019). The provision at issue here was intended to "enhance and improve women's health care," 155 Cong. Rec. S11987 (daily ed. Dec. 3, 2009) (statement of Sen. Mikulski), by filling gaps in the statute's other categories of preventive-care guidelines, *see, e.g.*, 155 Cong. Rec. S12271 (statement of Sen. Franken) (explaining that "several crucial women's health services are omitted" from the U.S. Preventive Services Task Force recommendations and that paragraph (4) "closes this gap"). And as the Supreme Court observed, a HRSA guideline would be arbitrary and capricious if the agency's explanation ran "counter to the evidence before [it]." *Little Sisters*, 140 S. Ct. at 2384 (brackets in original) (quotation marks omitted).

Although Plaintiffs want this Court to anticipate that the Supreme Court will reconsider existing nondelegation precedents based on the *Little Sisters* opinion's alleged "discomfort with the delegation" in this provision, Mot. at 26, this Court should not enjoin a statutory provision on the basis of predictions about what the Supreme Court will do in the future. As the Fifth Circuit recognized in *Big Time Vapes*, a lower court is supposed to apply existing Supreme Court precedent, "'not . . . read tea leaves to predict where it might end up.'" 963 F.3d at 447 (quoting

United States v. Mecham, 950 F.3d 257, 265 (5th Cir. 2020)). For that reason, this Court should apply existing nondelegation precedents and enter judgment against Plaintiffs on their nondelegation claims.

IV. PLAINTIFFS FAIL TO ESTABLISH A VIOLATION OF THE RELIGIOUS FREEDOM RESTORATION ACT

Plaintiffs Braidwood, Kelley Orthodontics, Kelley, Starnes, and the Maxwells ("Religious Objector Plaintiffs") contend that the PrEP coverage requirement under the Preventive Services Provision violates RFRA.[37] It does not.

RFRA provides that, with certain exceptions, "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability[.]" 42 U.S.C. § 2000bb-1(a). "To claim RFRA's protections, a person 'must show that (1) the relevant religious exercise is grounded in a sincerely held religious belief and (2) the government's action or policy substantially burdens that exercise by, for example, forcing the plaintiff to engage in conduct that seriously violates his or her religious beliefs.'" *United States v. Comrie*, 842 F.3d 348, 351 (5th Cir. 2016), quoting *Ali v. Stephens*, 822 F.3d 776, 782-83 (5th Cir. 2016).

But Religious Objector Plaintiffs fail to create a genuine issue of material fact that they meet RFRA's threshold requirement that the PrEP coverage requirement substantially burdens their religious beliefs. Religious Objector Plaintiffs assert that they are opposed for religious reasons to sexual activity outside of marriage between one man and one woman, which Defendants do not question. *See* Pls.' App'x 36, ¶ 12; Pls.' App'x 42, ¶ 12; Pls.' App'x 53, ¶ 12; Pls.' App'x

[37] In their summary judgment motion, Plaintiffs argue that coverage requirements for the HPV vaccine and screenings and behavioral counseling for sexually transmitted disease and drug use also violate RFRA. *See, e.g.,* Mot at 30. However, Plaintiffs' operative First Amended Complaint asserts a RFRA violation only with respect to the PrEP coverage requirement, and Defendants had no opportunity to seek discovery with respect to these newly-raised claims. *See* FAC ¶¶ 108-111. "A party may not raise a claim in its motion for summary judgment that was not asserted in the party's complaint." *See, e.g., Solferini as Tr. of Corradi S.p.A. v. Corradi USA, Inc.*, No. 4:18-CV-00293, 2020 WL 1511315, at *6 (E.D. Tex. Mar. 30, 2020). Accordingly, Plaintiffs' Motion for Summary Judgment should be denied to the extent it purports to assert a RFRA claim involving any preventive care service covered by 42 U.S.C. §300gg-13 other than PrEP.

59, ¶ 12; Pls.' App'x 70, ¶ 15. But Plaintiffs also make the unsupported *factual* claims that requiring or providing coverage "of PrEP drugs facilitates and encourages homosexual behavior, intravenous drug use and sexual activity outside of marriage between one man and one woman." Pls.' App'x 36, ¶ 13; Pls.' App'x 42, ¶ 13; Pls.' App'x 53, ¶ 13; Pls.' App'x 59, ¶ 13; Pls.' App'x 70, ¶ 16. This empirical assertion—which would likely require expert testimony to establish and to which Plaintiffs provide no basis for insight or personal knowledge—cannot be established by conclusory statements in Plaintiffs' declarations.

For the same reason, Plaintiffs' contention that "participating in a health insurance plan that uses [their] premiums to pay for coverage of PrEP drugs would make [them] complicit in these behaviors," is insufficient to establish that RFRA applies here. Religious Objector Plaintiffs offer no support for the factual claim that their health plans *do or will* use their premiums to pay for this coverage, so they cannot establish that the religious beliefs on which they premise their claims are or will be burdened by the PrEP coverage requirement. Indeed, no Religious Objector Plaintiff has presented any evidence that they have or are imminently likely to spend money that will be used to cover PrEP medications. To the contrary, each Religious Objector Plaintiff has conceded that they cannot identify *any* impact on their health insurance premiums arising from the requirement to cover PrEP drugs.[38] *See* APP 228, No. 12; APP 187, No. 13; APP 170, No. 12; APP 210, No. 13; APP 341, No. 12.[39] Moreover, while Plaintiffs claim that the PrEP coverage requirement

[38] Indeed, Plaintiff Kelley Orthodontics does not even offer health insurance to its employees and neither Plaintiff Kelley nor Plaintiff Starnes purchases health insurance for himself—not because of the PrEP requirement or any objections thereto, but because, five years before the PrEP requirement took effect "the premiums for health insurance that [Kelley] provided for [his] employees" increased. APP 187, No. 13; *see* APP 210, No. 13; APP 341, No. 13. These Plaintiffs can claim no burden on their religious beliefs from an insurance coverage requirement that applies to insurance that they have chosen not to obtain for other reasons.

[39] While Religious Objector Plaintiffs each substantively admit that they are unable to identify any impact on their insurance premiums from the PrEP coverage requirement by claiming they "lack knowledge" to respond to Requests for Admission, they served their requests for admission after the expiration of the 30 day period set forth in Rule 36 without requesting an extension, and so all Requests for Admission must also be deemed admitted in any event by operation of Rule 36(a)(3).

violates their religious beliefs because it puts them to a choice between "subsidizing lifestyles that violate their religious beliefs and foregoing health insurance," Plaintiffs Kelley and Starnes demonstrate why, for each of the individual Religious Objector Plaintiffs, this is not so. Both chose to forego ACA-compliant health insurance in 2016, years before the PrEP coverage requirement was set in motion by PSTF's "A" recommendation for PrEP medications in 2019—in order to participate in Christian bill-sharing services. *See* APP 210, No. 13; APP 341, No. 13. These bill-sharing services are not group health plans or health insurance subject to the requirements of the ACA (including the Preventive Services Provision), and thus Religious Objector Plaintiffs have available options to reduce the risk of medical expenses that are not subject to the Preventive Services Provision *at all*. *See generally* 42 U.S.C. § 300gg-19 (definitions of "group health plan" and "health insurance"); *cf.* Congressional Research Service, Applicability of Federal Requirements to Selected Health Coverage Arrangements at 15-16 (Nov. 13, 2019) (describing "Health Care Sharing Ministries" as "Noncompliant Health Coverage Arrangements" which "do not necessarily comply with" federal health insurance requirements). Thus, Religious Objector Plaintiffs are not required to choose between obtaining protection from significant medical expenses and "subsidizing" any lifestyles they oppose—they are at most required to choose between obtaining ACA-compliant health insurance and other forms of health coverage, just as they could choose before the ACA between plans that included certain services and others that did not.

In short, Religious Objector Plaintiffs have failed to create a genuine issue of material fact that the PrEP coverage requirement substantially burdens their religious beliefs—let alone establish that there is no genuine issue of material fact that it *does*—and judgment should be entered on Defendants' behalf on that basis.

See Fed. R. Civ. P. 36(a)(3); *see also* APP 389, 392 (31 days between August 30, 2021 service of Requests for Admission and September 30, 2021 responses).

Even if Religious Objector Plaintiffs could create a genuine issue of material fact as to whether the PrEP coverage requirement substantially burdens their religious beliefs, Plaintiffs still cannot prevail on their RFRA claim. Even in cases where a plaintiff satisfies RFRA's threshold requirement (which is not the case here), the government may substantially burden a person's exercise of religion where doing so "is in furtherance of a compelling governmental interest; and is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C §§ 2000bb-1(b)(1)-(2).

Plaintiffs' contention that there is no compelling governmental interest in ensuring coverage of PrEP is without merit. There can be no dispute that the government has a compelling interest in inhibiting the spread of fatal infectious diseases. *See, e.g., Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 26, 29 (1905) ("There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members. . . . [I]n every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand."); *Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015) ("[W]e agree with the Fourth Circuit, following the reasoning of *Jacobson* and *Prince*, that mandatory vaccination as a condition for admission to school does not violate the Free Exercise Clause."); *cf.*, *S. Bay United Pentecostal Church v. Newsom*, 985 F.3d 1128, 1142 (9th Cir. 2021) ("[T]he Supreme Court held that '[s]temming the spread of COVID-19 is unquestionably a compelling interest.'" (quoting *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020))).

HIV is unquestionably a fatal infectious disease. Since the first cases were reported in 1981, more than 700,000 persons in the US have died of AIDS—which is the most severe stage of HIV—and nearly 16,000 HIV positive people in the US and its territories died in 2019 alone. APP 380, ¶ 4. PrEP medications are remarkably effective at reducing the transmission of this fatal disease, potentially reducing transmission by as much as 99%. APP 381, ¶ 7. Expanding the use of PrEP

could have prevented an additional 17,000 HIV cases between 2015 and 2020. APP 382, ⁋ 8. Yet the expense of these medications can be prohibitive, costing in some cases $20,000. APP 383, ⁋ 13. Thus, expanding the use of PrEP medications by reducing the cost barriers to use of the medication will result in reduced transmission of the HIV virus, and ultimately fewer deaths from conditions related to that virus.

Further, because HIV is a contagious disease, the benefits of PrEP use are not limited to protecting those who take it. Any individual who does not become infected also cannot transmit the virus to others, who in turn cannot transmit it to still others, and so on. Thus, by reducing the likelihood that those taking it will be infected with HIV, PrEP also protects the broader public by reducing the likelihood that each person who takes it will infect others, slowing the spread of disease by a rate greater than the number of individuals who use it. For example, the PrEP coverage requirement encompasses coverage for monogamous married couples trying to conceive a child in which one of the partners is HIV positive. *See* APP 156, (PSTF PrEP recommendation for "[h]eterosexually active women and men who have . . . [a] serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)"). Since there is an increased risk of HIV acquisition for women during periods of conception, pregnancy, and breastfeeding, PrEP can help prevent maternal HIV infection and therefore the risk of transmitting HIV to a child through childbirth or breast feeding. *See* APP 380, ¶ 7.

The reduction of the spread of HIV not only makes a tangible difference in the lives of those who will be protected from infection, it also provides substantial cost savings, and concomitant savings of resources on the health system. For every HIV infection that is prevented, an estimated $510,000 is saved in the cost of providing lifetime HIV treatment, resulting in significant cost-savings for the health care system. APP 383, ⁋ 11. In sum, there is a compelling government interest not only in making PrEP medications widely available, but doing so without cost sharing for individuals.

Nor can Religious Objector Plaintiffs create a genuine issue of material fact with respect to the final prong of RFRA's test, *i.e.*, that the coverage requirement is the least restrictive means

of furthering the government's compelling interest. PrEP is by far one of the most effective measures to counter the spread of HIV infection. *See* APP 381, ¶ 7. Therefore, to advance the government's compelling interest in reducing HIV infection, it is essential to eliminate barriers to PrEP access and uptake, including by eliminating cost-sharing hurdles for medications and associated services for those who need PrEP. *See* APP 384, ¶ 14. Including a coverage-without-cost-sharing requirement for insurance plans is a critical means of achieving this objective, and it is necessary to reduce those barriers as broadly as possible.[40]

The only alternative Plaintiffs put forward in their brief as a potential less restrictive means is the proposal that having the government pay for all PrEP medications would be less restrictive on their exercise of religion than having the government require most insurers to do so. But Plaintiffs are precluded from offering this proposed alternative, having failed to do so in discovery when expressly asked to identify any means less restrictive to further the government's interest in preventing further transmission of the HIV virus. *See* APP 348, No. 3; APP 356, No. 3; APP 362, No. 3; APP 367, No. 3; APP 374, No. 3; *see also* Fed. R. Civ. P. 37(c)(1) ("If a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion. . . ."). Nor do Plaintiffs offer any explanation or statement in their declarations or elsewhere that this putative alternative would in fact be less restrictive on their religious beliefs. *See generally* Pls.' App'x.

Given the critical importance of reducing barriers to PrEP access to the extent possible, and the absence of any viable alternative proposal that Plaintiffs would concede would be less restrictive on their religious beliefs, judgment should be entered for Defendants on Plaintiffs'

[40] Plaintiffs note that some health plans—particularly grandfathered plans—are excluded by the ACA from the Preventive Services Provision's requirements. But grandfathered plans can be expected to decrease over time, rendering that exception temporary. As for the exemption for companies with less than 50 employees, it is unclear how this helps Plaintiffs, who concede that Plaintiff Kelley Orthodontics is in this category of companies; as Plaintiffs note, if such businesses do choose to offer health insurance, they must comply with ACA's requirements. *See* Mot at 8.

RFRA claim.[41]

CONCLUSION

For the reasons set forth above, Plaintiffs' motion for summary judgment (ECF No. 44) should be denied, Defendants' motion to for summary judgment should be granted, and judgment should be entered in favor of Defendants on Plaintiffs' remaining claims.

[41] If the Court should disagree, Plaintiffs' requested relief sweeps far too broadly. In their First Amended Complaint, Plaintiffs request that the court enjoin Defendants from enforcing the PrEP coverage requirement "against any individual or employer who objects to the coverage of PrEP drugs for sincere religious reasons[.]" FAC ¶ 112(f). But Plaintiffs have neither brought a class action nor sought class certification and the issues of individual religious belief and potential objections to the PrEP coverage requirement are individualized questions that require individualized determination and relief. Indeed, Plaintiffs initially brought a class action, but when amending their Complaint in response to Defendants' Motion to Dismiss chose to remove their class action allegations. *Compare* Compl. *with* FAC. Accordingly, any relief should be limited to the specific Plaintiffs that assert religious objections to PrEP coverage.

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Certificate of Service

On January 28, 2022, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties who have appeared in the case electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Christopher M. Lynch
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